# EXHIBIT A

Case No. C20184991
HON. JANET C. BOSTWICK

**MITCHELL & SPEIGHTS, LLC**
Steven C. Mitchell (AZ Bar No. 009775)
Samuel F. Mitchell
(*pro hac vice* to be submitted)
4854 E. Baseline Road, Suite 103
Mesa, AZ 85206
Tel: (602) 244-1520
Fax: (602) 267-9394
steve@mitchellspeights.com
sam@mitchellspeights.com

**ATTORNEYS FOR PLAINTIFF**

**SUPERIOR COURT OF THE STATE OF ARIZONA**
**IN AND FOR THE COUNTY OF PIMA**

TUCSON MEDICAL CENTER, a corporation,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY INC.; AMNEAL PHARMACEUTICALS, LLC. n/k/a AMNEAL PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; DEPOMED, INC. k/n/a ASSERTIO THERAPEUTICS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC;

Case No. _____

**COMPLAINT**

**(Violation of RICO, A.R.S. § 13-2314.04)**
**(Violation of AZ's Consumer Fraud Act, A.R.S. § 44-1522)**
**(Negligence)**
**(Wanton Negligence)**
**(Negligence Per Se)**
**(Negligent Marketing)**
**(Negligent Distribution)**
**(Nuisance)**
**(Unjust Enrichment)**
**(Fraud and Deceit)**
**(Civil Conspiracy)**
**(Fraudulent Concealment)**

**JURY TRIAL REQUESTED**

MALLINCKRODT, LLC; INSYS THERAPEUTICS, INC.; NORAMCO, INC.; MALLINCKRODT PLC; SPECGX, LLC; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC.; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA. INC.; ANDA, INC.; H. D. SMITH, LLC f/k/a H. D SMITH WHOLESALE DRUG CO.; HENRY SCHEIN, INC.; AMERISOURCEBERGEN DRUG CORPORATION; and CARDINAL HEALTH, INC.

Defendants.

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> The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time … A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also lead years later to blockbuster lawsuits and criminal cases against their companies.[1]

**COMPLAINT**

Plaintiff Tucson Medical Center brings this Complaint against Defendants AmerisourceBergen Drug Corporation; LLC; Cardinal Health, Inc.; Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Amneal Pharmaceuticals, LLC n/k/a Amneal Pharmaceuticals, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.; Depomed, Inc. k/n/a Assertio Therapeutics, Inc.; Anda, Inc.; H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co.; Henry Schein, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Insys Therapeutics, Inc., Allergan plc f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt Plc; Mallinckrodt LLC.; and SpecGx, LLC; (collectively "Defendants") under the Arizona RICO Act as codified in A.R.S. § 13-2314.04; Public Nuisance as codified in A.R.S. § 13-2917; Misbranding of Opioid Narcotics in accordance with A.R.S. § 32-1967; for violations of the Arizona Consumer Protection Act as set forth in A.R.S. § 44-1522(A); Civil Conspiracy; Negligence; Wanton Negligence; Negligence *Per Se*; Negligent Marketing; Negligent Distribution; Negligent Misrepresentation; Fraud and Deceit; and Unjust Enrichment seeking judgment against Defendants and in favor of Plaintiff; compensatory damages; treble damages; punitive damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief and alleges as follows:

[1] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* at 133 (Bloomsbury Press 2015) (hereinafter referred to as "Dreamland").

## INTRODUCTION

1. In the midst of a national opioid epidemic and related public health crisis, Tucson Medical Center stands out for the work it has done for its southern Arizona community and as a convener of community collaboration.

2. Tucson Medical Center is Tucson's locally governed nonprofit regional hospital and a community leader in Pima County where its main hospital is located and is nationally recognized in terms of health wellness and civic leadership. It is a vital link to the southern Arizona community to which it serves, and is a prominent voice among Arizona's hospitals

3. Tucson Medical Center is uniquely situated within southern Arizona. It provides medical services to 29 different zip codes which, in 2017 equated to 99,193 people seen in the emergency department, 33,727 in-patient admissions, 25,356 surgeries and 5,224 babies being delivered. Tucson Medical Center is the raw nerve center for medical care in southern Arizona.

4. But the opioid crisis has challenged its leadership skills, taxed its resources, and threatened its resolve to provide quality health care to anyone in trouble and in need of medical services. This crisis threatens Tucson Medical Center in a way that it has not previously experienced in over fifty years since its founding.

5. The bulk of the patients whom Tucson Medical Center serves, either directly or through its collaborations, are either uninsured or are covered by Medicare or Arizona's Medicaid program. Tucson Medical Center must invest into those programs each year to obtain such coverage.

6. Tucson Medical Center has addressed the problems that the opioid epidemic poses as it has addressed problems in the past: through collaboration and community building.

7. In 2018, Tucson Medical Center formed the Southern Arizona Hospital Alliance to address the opioid epidemic in the rural border areas outside of Tucson and to serve as a hub and to provide expert services and guidance to those communities and the critical care hospitals located in Benson, Bisbee, Safford and Willcox. The slogan of the Alliance is: "We're stronger when we work together." That strength is especially needed in the opioid crisis because opioid

related health care issues occur in urban and rural areas alike and in people of all ages, genders and ethnicity.

8. Tucson Medical Center is a member of the Mayo Clinic Care network, a national network of organizations committed to better serving patients and their families through collaboration. Members communicate with one another through telemedicine and tele-mentoring.

9. Tucson Medical Center participates in nearly 1,300 events that provide health education and information to the community, including a symposium for cancer survivors, screening seniors for stroke risk, supporting young girls in their first 5K race, and sharing bicycle and car safety equipment and tips with families

10. Annually the Tucson Medical Center Community Benefit Team participates in more than 100 events in which they provide a full range of services including on-site blood pressure checks, cardiac risk assessment, and life-saving education and information.

11. In 2017, the Community Benefit Team recognized substance abuse to be among the most crucial issues facing the community and Tucson Medical Center. In particular, opioid overdoses accounted for more than 66% of overdoses in Pima County in 2016 and 2017. Similarly, opioids led to a nearly two-fold increase in the number of emergency department visits and inpatient hospital stays. Julia Strange, vice president of Tucson Medical Center's Community Benefit team, stated that "[t]he opioid epidemic is dramatically impacting Pima County residents, providers, acute-care hospitals and law enforcement personnel. We are committed to working toward a solution as we consider the lives being lost and the broader costs to our communities."[2] In lockstep with Ms. Strange's comments, medical practitioners at Tucson Medical Center who encounter a patient with opioid addiction[3] have stated that these patients are a significant and growing cause for concern for the hospital and community.

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[2] 2017 Tucson Medical Center Report to Our Community, available at https://issuu.com/tucsonmedicalcenter/docs/tmc-270_rotc_2018_issuu.

[3] Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. Throughout this Complaint, "addiction" refers to the entire range of substance

12. In an effort to address the particularly difficult and distressing medical and social problems experienced by opioid dependent babies born to opioid addicted mothers, Tucson Medical Center opened an annex within its Neonatal Intensive Care Unit ("NICU") to provide specialized care for the babies and their mothers. Tucson Medical Center partnered with local behavioral health professionals to host on-site support groups, parenting classes and skills training for parents willing to address their substance abuse.

13. Tucson Medical Center also has developed surgical protocols that reduce the need for opioid narcotics during recovery and collaborated with other medical professionals to determine appropriate treatment guidelines for opioid usage for chronic pain in emergency settings.

14. As a result of these and other proactive measures, community benefit and charity care services that Tucson Medical Center provided represented 11.9% of its net revenues, or $63,559,138 dollars, in 2017. These monies touched the lives of approximately 383,000 patients and were used to cover costs incurred by the hospital for less than full payment, or no payment at all, for opioid-related medical services[4] it provided.

15. Opioid addiction is a battle between life and death, and the staff of Tucson Medical Center are on the frontline, fighting daily to save the lives of patients and community members. With the demand for services ever-increasing, Tucson Medical Center's resources are being stretched beyond their limit. This case takes aim at the primary cause of the opioid crisis: A False Narrative marketing scheme directly affecting hospitals like Tucson Medical Center who buy and

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abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

[4] Opioid-related medical services include, but are not limited to, oxygenation, intubation, surgery, removal of abscesses, antibiotic administration, admission to the hospital for prolonged antibiotic treatment, treatment of intranasal drug use, treatment of intravenous drug use, treatment of infection, treatment of septic embolisms, neurological evaluations, magnetic resonance imaging ("MRIs"), computed tomography scans ("CT scans"), drug tests, admission and monitoring in Intensive Care Unit, admission and monitoring in the Pediatric Intensive Care Unit, admission and monitoring in the Neonatal Intensive Care Unit and behavioral health monitoring and assessment.

administer opioids and provide medical care to increasing numbers of opioid affected patients, who usually cannot pay for their care. As described below, this False Narrative was created and implemented as a result of a conspiracy among and between the Marketing Defendants, the Distributor Defendants, and others. At its core, this scheme involved the false and deceptive marketing or prescription opioids, with the goal of increasing demand for and increasing sales of opioids. Tucson Medical Center brings this action to recover damages suffered as a consequence of the Defendants' actions (or lack thereof) so that it may continue to provide and expand care to the families and individuals who are fighting for their lives against opioid addiction.

## I. THE OPIOID CRISIS

16. Tucson Medical Center encounters patients with opioid addiction on a daily basis. It must deal with patients who have serious medical conditions that require extra care and expense because the patient is addicted to opioids. Consider a situation where two pregnant women present themselves to a hospital for treatment – a healthy expectant mother and a mother addicted to opioids. Regardless of whether either patient can pay, they both **must** be admitted under prevailing federal law, even though the hospital knows it may not be compensated in full, or perhaps at all, for its medical services. Both women give birth. If the mother with opioid addiction gives birth to a child with neonatal abstinence syndrome (NAS), that child enters this world kicking and screaming in pain as he or she immediately begins the addiction withdrawal process. At Tucson Medical Center, the child is taken to the neonatal abstinence syndrome annex ("NASA"), in which sophisticated medical equipment, supplies, and staff specially trained to treat the needs of babies with NAS and other opioid-related conditions treat and care for these babies on an individualized basis. This mother and baby, due to the intensive care and specialization required to appropriately treat them, may require months in the hospital to stabilize their complex medical issues. In contrast, the healthy mother's and child's stay in the hospital is usually confined to one to three days with much less supervision and significantly less costs. Ultimately, hospitals have a duty to treat both mothers and their babies, yet the cost to the hospital is much greater for the mother and baby with opioid addiction and related conditions. This, in turn, results in higher uncompensated

costs to the hospital due to the unsettling fact that the majority of mothers and babies with opioid addiction and related conditions are likely to be under or uninsured.

17. These two very different encounters play out daily at Tucson Medical Center and at hospitals throughout the State of Arizona. Between 2008 and 2014, the rate of Neonatal Abstinence Syndrome ("NAS") increased within Arizona by 245%[5]. Of that amount, 350 of these babies were born at Tucson Medical Center.

18. Hospitals—legally and morally—are compelled to act and treat patients with opioid- related conditions[6] and, as a result, have been directly damaged by the opioid epidemic. In addition to the cost of the opioid drugs themselves, hospitals within the State have incurred and continue to incur millions of dollars in damages for the costs of uncompensated care as a result of the unlawful marketing, distribution, and sale of opioids.

19. The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sale, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and the loss of life.[7] According to the Centers for Disease Control ("CDC"), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.[8]

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[5] Jennifer Dudek, MPH, *Neonatal Abstinence Syndrome and Newborn Drug Exposures Arizona Births, 2008-2014*, (July 2015), https://azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/substance-abuse/2014-nas-fact-sheet.pdf.

[6] "Opioid-related conditions" include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; Neonatal Abstinence Syndrome (NAS) or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, Hepatitis-C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiff's records as related to opioid use and abuse.

[7] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

[8] Centers for Disease Control and Prevention, *Prescribing Data, available at* https://www.cdc.gov/drugoverdose/data/prescribing.html, (last accessed August 1, 2018).

20. A particular tragedy of the opioid epidemic is that it has turned law-abiding citizens who experience routine injuries into drug addicts which, in many cases, has resulted in the total derogation of their lives.

21. Hospitals are struggling from the relentless and crushing financial burdens caused by the epidemic of opioid addiction. Every day across the United States, more than 115 Americans lose their lives after overdosing on opioids.[9] In Arizona, more than two Arizonans died each day during 2016 as a result of the opioid epidemic.[10] The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act ("ACA") are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-addicted patients admitted under the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd.[11]

22. According to the CDC, opioid overdoses killed more than 45,000 people over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history.[12] If current trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

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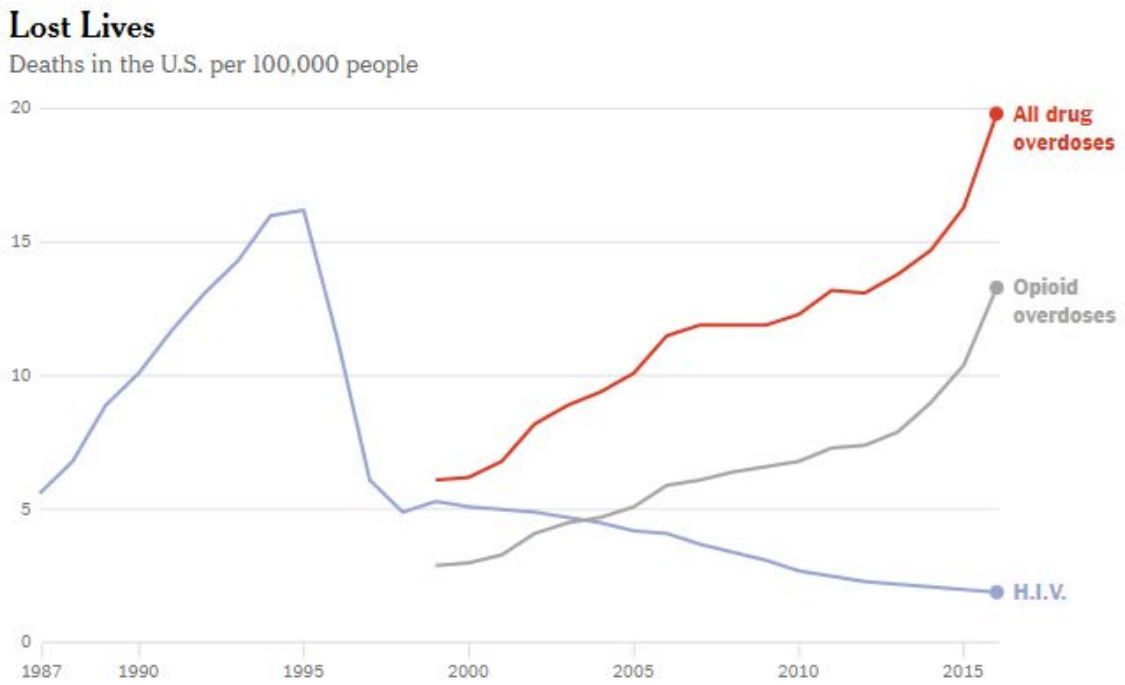
[9] Opioid Overdose Crisis, National Institute on Drug Abuse (revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one. ("Opioid Crisis, NIH").

[10] *Arizona State Senate*, 53rd Leg., 1st Special Session, Fact Sheet for S.B. 1001/H.B. 2001, *available at https://www.azleg.gov/legtext/53leg/1S/summary/S.100_ASENACTED.pdf*.

[11] American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, https://www.aha.org/guidereports/2018-03-02-aha-priorities-address-opioid-crisis, (last accessed August 1, 2018).

[12] The Editorial Board, *An Opioid Crisis Foretold*, THE NEW YORK TIMES (April 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html.




Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.[13]

23. Between the start of the century and the year 2014, opioid-related death rates have increased by 200%. Fourteen percent of that increase occurred between 2013 and 2014.[14]

24. The opioid epidemic is killing scores of individuals each and every day and as is having a similarly drastic impact on the total cost of medical care.

25. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[15] In many cases, heroin abuse starts with prescription opioid addiction.

[13] *Id.*
[14] *Id.*
[15] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. End. J. Med. 1480 (Apr. 14, 2016), doi: 10.1056/NEJMsr1601307, https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

26. According to the CDC, the United States is currently seeing the highest overdose death rated ever recorded.[16] As opioid-related deaths increase, the life expectancy in the United States decreases.[17]

27. Perhaps more than any other institution, hospitals directly bear the brunt of the opioid crisis. And on June 5, 2017, Governor Douglas Ducey declared a State of Emergency for the State of Arizona, finding reasonable cause to believe that Arizona's opioid epidemic causes disease, illness and health conditions, including death.[18]

28. On October 28, 2017, the President of the United States did the same, and declared the opioid crisis a public health emergency.[19]

29. This suit takes aim at the primary cause of the opioid crisis: A False Narrative marketing scheme, in which the distributors joined and conspired, involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase demand for and sale of opioids and opioid prescriptions.

30. On the demand side, the Defendants who manufacture, sell and market prescription opioid pain killers (the "Marketing Defendants") precipitated the crisis. These opioids have various brand names and generic names, and include "OxyContin," fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign

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[16] Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, The GUARDIAN (March 6, 2018). https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc.

[17] National Center for Health Statistics, Life Expectancy, *available at* https://www.cdc.gov/nchs/fastats/life-expectancy.htm, (last accessed August 1, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids, (March 18, 2018), https://www.cdc.gov/media/releases.2018/p0329-drug-overdose-deaths.html.

[18] Declaration of Emergency and Notification of Enhanced Surveillance Advisory, *available at* https://azgovernor.gov/sites/default/files/related-docs/opioid_declaration.pdf.

[19] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically—but untruthfully—asserted that the risk of addiction was low when opioids were used to treat chronic pain and overstated the benefits and trivialized the risk of the long-term use of opioids.

31. The Marketing Defendants' goal was simple: dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pain, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

32. The Distributor Defendants saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities under the Controlled Substance Act, and flooded affected areas with opioids while knowing they were contributing to, but profiting from, widespread addiction and human misery.

33. And Defendants succeeded. Opioid abuse has quickly become one of the nation's most pressing health management issues, not only because of its toll on patients, but increasingly because of the financial impact on hospitals and the rest of the healthcare system.[20]

34. The Marketing Defendants and Distributor Defendants extract billions of dollars of revenue from the addicted American public while hospitals sustain tens of millions of dollars of losses caused as a result of the reasonably foreseeable consequences of the prescription opioid addiction epidemic. In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme. Defendants knew that but for the hospitals providing at least some aspect

[20] Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse, (last accessed on August 1, 2018).

of a safety net, the number of overdose deaths and other related health consequences arising from opioid addictions would have even been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have been swifter and far more certain.

35. The statistics are startling. Adult hospitalizations due to opioid addiction doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.[21]

36. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64%, and the rate of opioid-related emergency department (ED) visits nearly doubled.[22]

37. The average health care costs for those diagnosed with an opioid use disorder were 8 times higher than those without an opioid use disorder.[23]

38. The cost to hospitalize those with opioid addiction has more than tripled in a decade, up to nearly $15 billion in 2012. Similarly, the number of patients hospitalized due to the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.[24]

39. Private insurance covers only a portion of those costs. The burden is carried by the hospitals, patients, and government programs.[25] In 2012, hospitals provided almost $15 billion for

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[21] *Id.*

[22] Audrey J. Weiss, et al, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

[23] Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in Journal of Managed Care Pharmacy, Vol. 11, No. 6 July/August 2005, at 469.

[24] Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs, (last accessed on July 11, 2018).

[25] *Id.*

opioid-related inpatient care, more than double of what they billed in 2002.[26] A substantial portion of these costs were under-insured or unreimbursed.

40. In 2012, an average hospital stay for a patient with an opioid-related condition cost about $28,000 and only about 20% of the discharges related to those incidents were covered by private insurance. The number increased to $107,000 if there was an associated infection, with merely 14% covered by insurance.[27]

41. Patients with complex opioid addiction-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals. In southern Arizona, there is nowhere for these patients to go other than hospitals due to the behavioral and security issues that are often associated with those who are addicted to opioids. As a result, they wind up staying in hospitals longer, resulting in the cost of care going up.[28]

42. The cost of treating opioid overdose victims in hospital intensive care units jumped 58% in a seven-year span. Between 2009 and 2015, the average cost of care per opioid overdose admission increased from $58,000 to $92,400. This was during a period where the overall medical cost escalation was about 19 percent. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.[29]

## II. IMPACT OF OPIOIDS ON ARIZONA HOSPITALS

43. Because of Defendants' conduct, the opioid epidemic is placing an increasing strain on the overburdened health care system in Arizona.

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[26] Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/.

[27] *Id.*

[28] https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/ last accessed on July 11, 2018.

[29] Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), https://www.statnews.com/2017/08/11/opioid-overdose-costs/.

44. The Marketing Defendants and Distributor Defendants have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

45. The misrepresentations of Marketing Defendants and Distributor Defendants and others prompted Arizona health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants and Distributor Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These Defendants' harms were compounded by supplying opioids beyond what the market could bear, funneling so many opioids into Arizona communities that the product could only have been diverted and used illicitly. The massive quantities of opioids that flooded into Arizona as a result of Defendants' wrongful conduct —431 million doses in 2016, or enough for every Arizonan to have a two-and-a-half-week supply—has devastated communities across this State, especially the southern Arizona community served by Tucson Medical Center.

46. The deceptive marketing campaign of the Marketing Defendants and Distributor Defendants substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages 30 and 44, and nearly 30% of the population over 45 have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include a prescription of an opioid.

47. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death through the United States, including Arizona. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[30]

[30] *America's Addition to Opioids: Heroin and Prescription Drug Abuse*, U.S. Senate, Caucus on

48. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[31]

49. In a 2016 report, the CDC explained that "[o]piod prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[32] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[33]

50. Defendants' practice of continually filling opioid prescriptions has enabled an oversupply of opioids to communities, including the community that Tucson Medical Center serves. Defendants had financial incentives to distribute higher volumes and not report suspicious behavior or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the

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International Narcotics Control, 113th Cong., at 3 (May 14, 2014) (statement). Testimony of Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, *available at* https://www.hdsl.ord/?abstract&did=754557.

[31] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *available at* http://www.turntheriderx.org/ (last accessed July 23, 2018).

[32] Rose A. Rudd, et al., Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 (Jan. 1, 2016), Morbidity and Mortality Weekly Report, 64(50);1378-82, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[33] *Id.*

difference as additional profit. Further, either explicitly or implicitly, all Defendants in this action worked together to ensure that profits remained artificially high.

51. Arizona has seen a 74% increase in opioid overdoses between 2013 and 2017 and this disturbing trend shows no signs of slowing down.[34] Between June 2017 and September 20, 2018, the State of Arizona experienced 2,258 deaths due to suspected opioid overdose, the highest number of deaths in more than a decade.[35] The county in which Tucson Medical Center is located, Pima County, has the highest incidences of drug-induced death (21.9/100,000), opiate/opioid death (14.9/100,000), pharmaceutical opioid death (11/100,000), and heroin related death (4.1/100,000) in the State.[36] Overdose deaths in Pima County have increased 18% from 2010 (222) to 2016 (263), with 67% of the deaths in 2016 being caused by an opiate compound.[37]

52. The 2016 Arizona Opioid Report found that 75% of heroin users started with opioid pain killers. In fact, people who become addicted to opioid painkillers are 40 times more likely to become addicted to heroin. And the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

53. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid approved for cancer pain, which has made its way into Arizona communities. According to physicians at Tucson Medical Center, nearly all heroin in southern Arizona contains fentanyl.

54. In addition, doctors associated with Arizona-based Defendant, Insys Therapeutics, Inc., have led efforts to prescribe its product Subsys in an off-label use for chronic pain to patients

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[34] S.B. 1001, 53rd Leg., 1st Spec. Sess. (AZ. 2018).
[35] Arizona Department of Health Services, Real Time Opioid Data, https://www.azdhs.gov/prevention/womens-childrens-health/injury-prevention/opioid-prevention/index.php (last assessed October 9, 2018).
[36] Gregory L. Hess, M.D., Marcy Flanagan, Danna Whiting, M.S., *Memorandum Re: Update on Opioid Response in Pima County* (Aug. 29, 2017), https://www.scribd.com/document/357813000/Update-on-Opioid-Misuse-in-Pima-County#fullscreen&from_embed.
[37] *Id.*

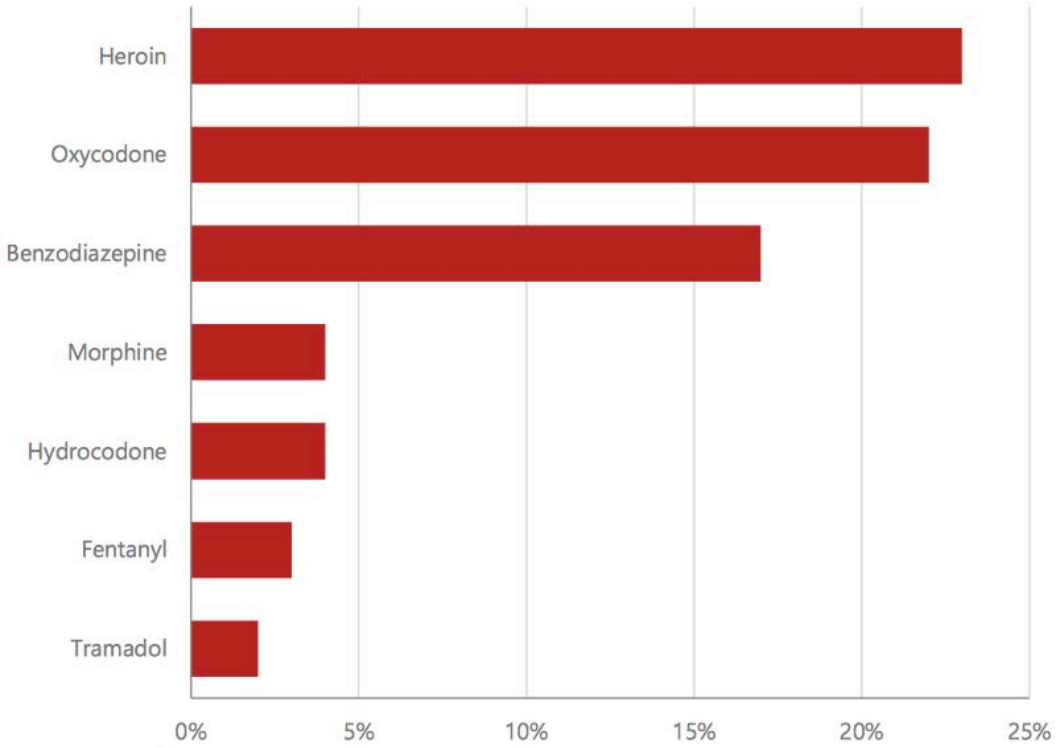
in the service area of Pima County. Subsys is a fentanyl spray applied under the tongue, allowing fentanyl to reach the bloodstream. One of the three doctors named as defendant in the Attorney General for the State of Arizona's recent Complaint against Insys, Dr. Sheldon Gingerich, is located in Pima County. According to that Complaint, Dr. Gingerich wrote 741 Subsys prescriptions between March 2012 and 2017, the third-highest number of Subsys prescriptions in Arizona.[38] Tucson Medical Center treated patients addicted to fentanyl from Subsys off-label use.[39]

55. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that is typically used in veterinary medicine to sedate elephants and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. "People have to understand there's absolutely zero use for humans. None. There's no use in humans unless you're trying to kill them."[40]

56. Statistics tell a consistent and tragic story. Drug overdoses now take more lives than car crashes in Arizona. Between June 2017 and January 2018, 5,202 Arizonans suffered a suspected overdose from opioids and 455 Arizona babies were born addicted to opioids.

57. The table below illustrates the number of verified opioid overdoses by specific drugs in Arizona from June 15, 2017 to December 31, 2017:[41]

[38] Complaint at ¶¶ 215-31, *State ex rel Brnovich v. Insys Therapeutics, Inc.*, Case No. CV2017-012008 (Maricopa Co., Ariz. Aug. 30, 2017).
[39] *Id.*
[40] Evan Schriber, *Carfentanil Death Has Law Enforcement Warning of Danger*, TUCSON NEWS NOW (Apr. 16, 2018) *available at* *http://www.tucsonnewsnow.com/story/37971249/carfentanil-death-has-law-enforcement-warning-of-danger* (last accessed July 23, 2018).
[41] Arizona Department of Health Services, 2018 Update: Opioid Emergency Declaration & Action Plan Implementation, Appendix A – Highlighted Opioid Data, https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/action-plan/appendix-a-feedback.pdf (last accessed July 23, 2018).)




58. Across the state, Arizona families and communities face heartbreaking tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; other have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Tucson Medical Center.

59. As communities work to restore their lives, the opioid epidemic continues to outpace their efforts. Opioid addiction is now the primary reason that Arizonans seek substance abuse treatment and collectively the State invests $265 million per annum in substance abuse treatment and prevention.

## III. FINANCIAL IMPACT OF DEFENDANTS' ACTIVITIES ON PLAINTIFF

60. Plaintiff Tucson Medical Center was incorporated in 1944. It is a nonprofit community hospital serving residents throughout southern Arizona. Tucson Medical Center is a

639-bed facility, including both an in-patient and retail pharmacy, an emergency department, and a 42-bed NICU.

61. Plaintiff has treated, and continues to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) Hepatitis C, HIV and other infections occurring as a result of I.V. drug use; (4) neonatal treatment in its NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, and lengthy; and (5) psychiatric and related treatment for patients with opioid addiction who present in need of mental health treatment programs.

62. Tucson Medical Center has incurred and continues to incur substantial unreimbursed costs for its treatment of patients with opioid-related conditions. These patients with opioid-related conditions seek treatment from Tucson Medical Center as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Tucson Medical Center's monetary losses with respect to treatment of these patients are foreseeable to Defendants and are the proximate result of Defendants' acts and omissions specified herein.

63. Tucson Medical Center also has incurred and continues to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid affected. Surgical procedures on opioid affected patients have been and are complicated and costly and require special protective measures and related prescription drugs.

64. Additionally, individuals with opioid addiction have presented and continue to present themselves to Tucson Medical Center claiming to have illnesses and medical problems in an effort to obtain opioids. Tucson Medical Center has incurred and continues to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

65. The costs incurred by Tucson Medical Center are the direct and proximate result of the False Narrative campaign described below and the opioid epidemic created and engineered by Defendants.

66. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of patients with opioid-related conditions going to hospitals for treatment, including to Tucson Medical Center. It was also foreseeable to Defendants that Tucson Medical Center would suffer substantial monetary losses because of the opioid epidemic, since hospitals are on the front-line of treatment for these patients and must bear the additional costs of treatment.

67. It was also foreseeable that Defendants would face claims from hospitals for their costs from treating opioid-related conditions. Hospital lien laws enacted in Arizona and in many other states provide hospitals with the right to record a medical lien for the costs they expend in the care and treatment of an injured patient and enforce that lien.

68. Tucson Medical Center has purchased and continues to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Tucson Medical Center, its pharmacy representatives and its doctors. Defendants directly marketed their opioid products through the False Narrative described below. Tucson Medical Center is a direct customer and victim of Defendants' false, deceptive, and unfair marketing of opioids described hereafter.

69. Tucson Medical Center has purchased opioids from Defendants, has used them as falsely and deceptively marketed by Defendants, and has suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint.

70. Tucson Medical Center would not have purchased the quantity of opioids it had from Defendants had it known the truth about Defendants' false marketing scheme, i.e. that Defendants' claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded, as described herein.

71. Tucson Medical Center brings this civil action to recover monetary losses that it has incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

72. Tucson Medical Center brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were unlawful.

73. Tucson Medical Center also brings this suit against the wholesale distributors of these highly addictive drugs. In addition to participating in the False Narrative campaign described below, the Distributor Defendants (along with the Manufacturers) unlawfully breached their legal duties under Arizona law to monitor, detect, investigate, report, and refuse to fill suspicious orders of prescription opiates, which enabled the manufacturers' deceptive advertising to increase sales and distribution of their products to hospitals, including Plaintiff Tucson Medical Center.

## IV. THE ROLES OF DEFENDANTS IN CAUSING AND PERPETUATING THE OPIOID CRISIS

74. The Marketing Defendants' push to increase opioid sales worked. Through publications and websites, endless streams of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

75. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know should be necessary for legitimate medical uses, while failing to report, and take steps to halt, suspicious orders when they

were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

76. From the day they made the pills to the day those pills were consumed in each community, the Marketing Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

77. Defendants systematically and repeatedly disregarded the health and safety of the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

78. Corporate greed and callous indifference to the known, serious potential for human suffering have caused this public health crisis. Defendants unleashed a healthcare crisis that has had far-reaching financial and social consequences in this country, including opioid addiction and death.

79. The Marketing Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

80. The Marketing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants for their support of the Marketing Defendants' marketing messages.

81. The Marketing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Marketing Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors, and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Marketing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

82. Each Marketing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.[42]

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[42] *See* Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed August 1, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines.

83. In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[43]

## JURISDICTION AND VENUE

84. This Court has subject matter jurisdiction pursuant to A.R.S. Const. Art. 6 § 14.

85. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Arizona and purposefully directed their actions towards Arizona, voluntarily submitted to the jurisdiction of Arizona when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Arizona necessary to constitutionally permit this Court to exercise jurisdiction.

86. In addition, Defendant Insys is a Delaware corporation with its principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

87. Venue is proper in this Court pursuant to A.R.S. § 12-401(10) because the foundation of the trespass for which this action in damages lies, may be brought in the county in which the trespass was committed. Trespass has been long construed to mean "tort." *Zuckernick v. Roylston*, 684 P.2d 177, 178 (Ariz. Ct. App. 1984).

## PARTIES

### I. PLAINTIFF

88. Plaintiff Tucson Medical Center is an Arizona nonprofit corporation located at 5301 East Grant Road, Tucson, Arizona 85712. Plaintiff is a 639-bed facility.

### II. DEFENDANTS

#### A. Marketing Defendants

##### 1. Purdue and Associated Companies

89. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

[43] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n. 32.

90. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

91. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

92. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including to Plaintiff. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

93. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

**2. Cephalon and Associated Companies**

94. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

95. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August

2016. Teva USA and Cephalon are collectively referred to herein as "Teva."

96. Defendant Teva Pharmaceuticals USA, Inc. ("TEVA USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

97. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[44] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[45] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a $425 million fine.[46]

98. Teva USA, and Cephalon, Inc. (collectively Cephalon) work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its "specialty medicines" division. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide,

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[44] *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009),* ACTIQ PI/Med Guide, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last accessed August 1, 2018).

[45] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011),* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last accessed August 1, 2018).

[46] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

99. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[47] Teva USA's parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon's and Teva USA's sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora.[48]

100. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to herein as "Cephalon."

101. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact deceptively to promote and maximize the use of opioids.

### 3. Janssen and Associated Companies

102. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

103. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

104. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

105. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had

[47] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last accessed August 1, 2018).

[48] Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf

been part of J&J's opium processing by making active pharmaceutical ingredients ("APIs") for opioid painkillers.

106. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

107. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho- McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

108. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

109. Janssen made thousands of payments to physicians nationwide, including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

110. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.[49] Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document.

[49] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

111. The "*Every Day Health Care Compliance Code of Conduct*" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "*Pharmaceutical Companies of Johnson & Johnson*" and as one of the "*Johnson & Johnson Pharmaceutical Affiliates.*" It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

**4. Endo and Associated Companies**

112. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

113. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

114. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

115. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from

2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.[50] In response to the FDA's request, Endo removed Opana ER from the market in July 2017.[51] Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

116. Endo made thousands of payments to physicians nationwide, including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

**5. Insys Therapeutics, Inc.**

117. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys.

118. Insys made thousands of payments to physicians nationwide, including to doctors in Pima County and other areas of Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

119. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

120. In 2016, Insys made approximately $330 million in net revenue from Subsys.

[50] Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[51] Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er.

121. Insys promotes, sells, and distributes Subsys throughout the United States, and extensively in Arizona.

122. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. The Arizona Attorney General has brought a Consumer Fraud Action against Insys, its company executives and certain doctors who aided its alleged nationwide scheme in which it deceived insurers, patients and doctors, included those in area that plaintiff serves. One of the doctors named as a defendant in that suit practiced in Pima County and wrote prescription for off-label use of Subsys to patients there.

**6. Abbott Laboratories**

123. Defendant, Abbott Laboratories, is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Abbott Laboratories and Abbott Laboratories, Inc., are both registered to do business in the State of Arizona. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

124. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

125. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

126. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

127. Abbott and Purdue's conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America's Opioid Epidemic*:

> Abbott and Purdue actively misled prescribers about the strength and safety of the pain killer [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction…. One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent.[52]

**7. Amneal Pharmaceuticals, LLC**

128. Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a Delaware limited liability company with its principal place of in New Jersey. Amneal Pharmaceuticals, LLC merged with Impax Laboratories, Inc., in May 2018 to become Amneal Pharmaceuticals, Inc. At all relevant times, Amneal has sold prescription drugs including opioids in Arizona and across the United States.

**8. Depomed, Inc.**

129. Defendant Depomed, Inc. k/n/a Asserto Therapeutics, Inc. ("Depomed") is a Delaware corporation with its principal place of business in Lake Forest, IL. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescriptions drugs in Arizona and across the United States. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from

[52] American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, Psychology Today, Oct. 28, 2016, https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic.

Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

**9. Mallinckrodt Entities**

130. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC (together with Mallinckrodt plc and SpecGx LLC, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiff. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

131. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

132. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt also estimated, based on IMS Health

data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[53]

133. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

134. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (Hydromorphone hydrochloride, extended release), Roxicodone (Oxycodone hydrochloride), Xartemis XR (Oxycodone hydrochloride and acetaminophen), Methadose (Methadone hydrochloride), Generic (Morphine sulfate, extended release, Morphine sulfate oral solution, Fentanyl transdermal system, Oral transmucosal fentanyl citrate, Oxycodone and acetaminophen, Hydrocodone bitartrate and acetaminophen, Hydromorphone hydrochloride, Hydromorphone hydrochloride, extended release, Oxymorphone hydrochloride, Methadone hydrochloride. Schedule III: Buprenorphine and naloxone. Unscheduled: Naltrexone hydrochloride.

135. Mallinckrodt made thousands of payments to physicians nationwide, including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids

### 10. Actavis and Associated Companies

136. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

137. Defendant Actavis plc acquired Defendant Allergan plc in March 2015, however the combined company changed its name to Allergan plc in January 2013.

[53] Mallinckrodt plc 2016 Form 10-K.

138. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then changed the name to Actavis plc in October 2013.

139. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

140. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

141. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

142. Each of these Defendants is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States.

143. Defendant Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Actavis") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including to Plaintiff.

144. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

145. Actavis made thousands of payments to physicians nationwide including in Arizona, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

146. Collectively, Purdue, Actavis, Amneal, Cephalon, Janssen, Depomed, Endo, Insys, Abbot, and Mallinckrodt are referred to as "Marketing Defendants."

**B. Distributor Defendants**

147. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with Arizona law. The Distributor Defendants are engaged in "wholesale distribution," as defined under Arizona law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiff's community.

**1. AmerisourceBergen Drug Corporation**

148. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Tucson Medical Center.

149. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

150. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."[54]

**2. Anda, Inc.**

151. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest

[54] AmerisourceBergen, 2016 Summary Annual Report, http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb (last accessed August 1, 2018).

distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e. Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Arizona and within the communities served by Tucson Medical Center.

**3. Cardinal**

152. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of $121.5 billion.

153. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over $120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Arizona, and has distributed opioids nationwide.

**4. H. D. Smith, LLC**

154. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. ("H. D. Smith") through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Arizona and the community served by Tucson Medical Center. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. has been restructured and its currently doing business of H. D. Smith, LLC's sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D.

Smith. At all relevant times, H. D. Smith distributed prescription opioids throughout the United States including in Arizona.

**5. Henry Schein Entities**

155. Henry Schein, Inc. (Henry Schein) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein, Inc. is incorporated in Delaware, with its principal place of business located in Melville, New York.

156. Henry Schein, Inc. distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

157. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within the State of Arizona and Pima County in particular.

158. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

159. Cardinal, Anda, H. D. Smith, Henry Schein and AmerisourceBergen are collectively referred to as the "Distributor Defendants."

**C. Defendants' Agents**

160. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

### 1. Doe Defendants

161. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Tucson Medical Center, who therefore sues these Defendants by fictitious names. Tucson Medical Center will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

## FACTUAL BACKGROUND

## III. THE HISTORY OF OPIOIDS

162. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

163. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.[55]

164. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

165. Opioids are regulated as controlled substances. Under Arizona law, opioids such as oxycodone and hydrocodone are specifically defined among those drugs labeled "narcotics." A.R.S. § 13-3401. Any person in Arizona, and outside Arizona, that "sells a narcotic or other controlled substance… within or into this state shall hold a valid board-issued permit" issued by the Arizona Board of Pharmacy. A.R.S. § 32-1927.03. *See also* A.R.S. § 36-2522 (A) ("Every

[55] Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

person who manufactures, distributes, dispenses, prescribes or uses for scientific purposes any controlled substance within this state or who proposes to engage in the manufacture, distribution, prescribing or dispensing of or using for scientific purposes any controlled substance within this state must first: 1. Obtain and possess a current license or permit as a medical practitioner as defined in § 32-1901 or as a pharmacy, pharmacist, manufacturer or wholesaler pursuant to title 32, chapter 18. 2. Be a registrant under the federal controlled substances act (P.L. 91-513; 84 Stat. 1242; 21 U.S.C § 801 *et seq.*").

166. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. *See* A.R.S. §§ 36-2512-2516.

167. Opioids generally have been categorized as Schedule II, for purposes of Arizona law, although some are classified as Schedule III drugs. A.R.S. § 36-2513(A). Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Except in emergencies, Schedule II drugs may not be dispensed without a prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by the state and registered with the DEA. A.R.S. § 13-3625(C).

168. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids

continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

169. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

170. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

171. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

172. As one doctor put it, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

## IV. THE OPIOID EPIDEMIC

173. Prescription opioids have become widely prescribed. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of

hydrocodone every 4 hours for 1 month.[56]

174. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.[57] Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.[58]

175. In 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription

[56] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/.

[57] Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true.

[58] Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), DOI: 10.1001/jama.2017.16190, https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true.

painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[59]

176. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more likely to be addicted to heroin.[60] According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.[61]

177. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.[62]

178. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[63]

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[59] *See* Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

[60] *See* Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last accessed August 1, 2018).

[61] Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf.

[62] Smith, Mitch. *Fentanyl Used to Execute Nebraska Inmate, in First for U.S.,* (Aug. 14, 2018), https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html.

[63] Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

179. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[64]

180. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[65]

181. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[66] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[67]

182. In 2016, the President of the United States officially declared an opioid and heroin epidemic.[68]

## V. OPIOIDS IN CONGRESS

183. Congressional interest in the opioid crisis is intense and proceeding at a vigorous pace. During the current congressional term, multiple committees in the House and Senate conducted dozens of hearings exploring the issue from almost every angle, including effects on

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[64] *See* Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[65] *See* Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, http://www.nejm.org/doi/full/10.1056/NEJMra1507771, (hereinafter "Volkow & McLellan").

[66] *Id.*

[67] *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, *available at* https://www.ncbi.nlm.nih.gov/pubmed/27623005.

[68] *See* Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week"), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf.

the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Two congressional committees are taking the lead to enact legislation to address the crisis: the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor and Pensions (HELP). In April 2018, the HELP Committee passed a bipartisan, comprehensive bill to address the opioid crisis and a Subcommittee of the Energy and Commerce Committee passed over 50 bills to combat the crisis, most on a bipartisan vote.

## VI. OPIOIDS IN ARIZONA

184. The opioid epidemic is of particular interest to the Arizona Legislature and Executive. On January 22, 2018, Governor Ducey called a Special Session of the Legislature to provide immediate consideration of legislation, The Arizona Opioid Epidemic Act, to combat the opioid epidemic, stating "Today, Arizona is taking immediate and aggressive action against the opioid epidemic… The time to act is now."[69] The all-hands-on-deck approach calls upon medical officials, law enforcement, community leaders, chronic pain suffers, pharmacists, victims, individuals addicted to opioids, substance abuse treatment experts and others to work collaboratively to combat the epidemic within Arizona that caused, between June 2017 and January 2018, a reported 812 deaths, 5,202 overdoses, 455 babies born addicted to opioids, and more than 6,000,000 opioids to be prescribed by four doctors in a county with a population of 200,000 people.[70] The Act was passed with unanimous support in the Arizona House and Senate and was signed into law by Governor Ducey on January 26, 2018.

## VII. THE MARKETING DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

185. The opioid epidemic did not happen by accident.

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[69] *See* News Release, *Governor Ducey: "The Time To Act Is Now,"* (available at https://azgovernor.gov/governor/news/2018/01/governor-ducey-time-act-now)

[70] Arizona Opioid Epidemic Act. (Available at https://azgovernor.gov/sites/default/files/related-docs/arizona_opioid_epidemic_act_policy_primer.pdf).

186. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

187. Each Marketing Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

188. The Marketing Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

189. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[71] In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids

[71] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[72] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

190. The Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

191. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

192. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

193. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer

[72] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n. 32.

protection laws and regulations. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

## VIII. EACH MARKETING DEFENDANT USED MULTIPLE AVENUES TO DISSEMINATE THEIR FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS.

194. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's community.

195. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by the drug manufacturers' corporate headquarters. This comprehensive approach ensures that the Marketing Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

196. The Marketing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

### A. Direct Marketing

197. The Marketing Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;

b. To the extent there is a risk of addiction, it can be easily identified and managed;

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;

d. Opioid withdrawal can be avoided by tapering;

e. Opioid doses can be increased without limit or greater risks;

f. Long-term opioid use improves functioning;

g. Alternative forms of pain relief pose greater risks than opioids;

h. A version of Oxycontin marketed by Purdue was effective in providing 12-hour pain relief; and

i. New formulations of certain opioids successfully deter abuse.

198. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

199. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

### 1. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low

200. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

201. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

202. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[73] and the risk substantially increases with more than three months of use.[74] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[75]

#### a. Purdue's Misrepresentations Regarding Addiction Risk

203. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this

[73] FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).
[74] CDC Guideline at 21.
[75] *Id.* at 2.

"research" in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine ("NEJM") in 1980.

204. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[76] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

205. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[77]

206. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its

[76] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[77] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail Of Addiction And Death*, 174 (Rodale 2003) (herein after "Pain Killer").

source was a letter to the editor, not a peer-reviewed paper.[78] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

207. In 1996, Defendant Purdue made a deal with Pharmaceutical giant, Abbott Laboratories, under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals.[79]

208. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos states "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*"[80] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[81]

209. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-

[78] J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

[79] "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies." 2002 Purdue Budget Plan, https://khn.org/news/purdue-and-the-oxycontin-files/ (last visited Aug. 20, 2018) (emphasis added).

[80] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI, (last accessed August 1, 2018) (emphasis added).

[81] Keefe, *Empire of Pain.*

paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[82]

210. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[83]

211. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[84]

212. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[85]

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[82] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[83] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[84] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

[85] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and*

213. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.* In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

214. Sales representatives marketed OxyContin as a product "to start with and to stay with."[86] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[87] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[88]

215. Purdue, through its unbranded website *Partners Against Pain*,[89] stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical

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*Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

[86] Keefe, *Empire Of Pain.*

[87] *Pain Killer, supra* n. 79, at 102.

[88] *Id.*

[89] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial,

problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids."

216. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[90] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

217. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

218. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

219. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

220. In 2001, Purdue revised the indication and warnings for OxyContin.

221. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially not harmful."

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[90] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

**b. Endo's Misrepresentations Regarding Addiction Risk**

222. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

223. Until April 2012, Endo's website for Opana, www.opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

224. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

225. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below.

226. APF conveyed through its National Initiative on Pain Control ("NIPC") and its website *Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

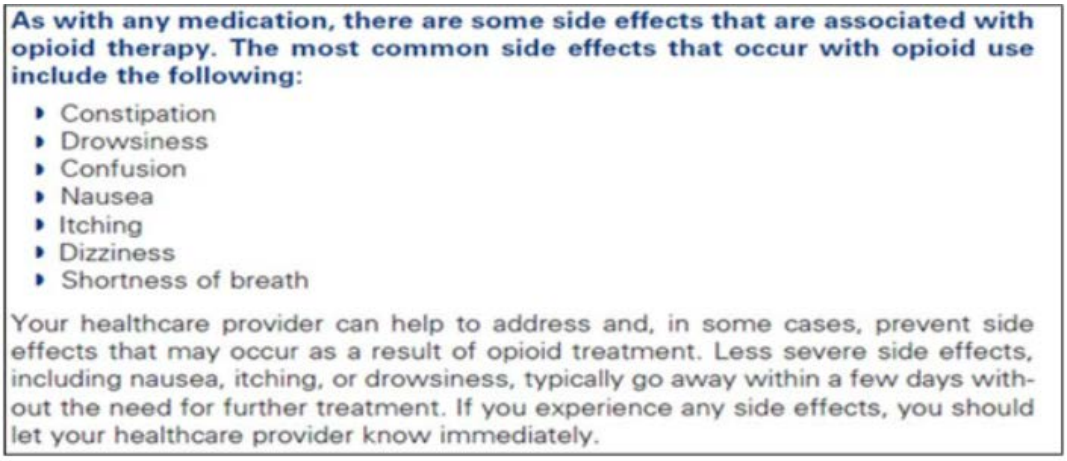
227. Another Endo website, *PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

228. A brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," an Endo-sponsored NIPC, stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

> In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic

> brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

229. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:



**As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

### c. Janssen's Misrepresentations Regarding Addiction Risk

230. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding addiction."

231. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

232. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[91]

[91] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

233. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.


234. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

**d. Cephalon's Misrepresentations Regarding Addiction Risk**

235. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options*: *A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

236. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the non-cancer patient population. . . . The continued stigmatization of opioids and

> their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[92]

**e. Mallinckrodt's Misrepresentations Regarding Addiction Risk**

237. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

238. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

239. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed

[92] Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, http://www.medscape.org/viewarticle/449803, (last accessed July 27, 2017).

appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy." "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

c. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

d. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

e. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

f. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

240. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain* and *Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

241. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic

of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

### 2. Falsehood #2: To The Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

242. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

243. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. Janssen, on its website *PrescribeResponsibly.com*, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[93] The website, which directly provides screening tools to prescribers for risk assessments,[94] includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[95]

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[93] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction (last modified July 2, 2015).

[94] Risk Assessment Resources, http://www.prescriberesponsibly.com/risk-assessment-resources (last accessed August 1, 2018).

[95] *Id.*

244. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

245. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

246. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

247. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

248. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care*: *Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

249. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially

limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

### 3. Falsehood #3: Signs of Addictive Behavior are "Pseudoaddiction," Requiring More Opioids

250. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[96] In other words, people on prescription opioids who exhibited classic signs of addiction— for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

251. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

252. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

[96]David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.)

253. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

254. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the kit was in use from roughly 2011 through at least June 2016.

255. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

256. Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[97] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

[97] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

257. The FAQs section of *pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

258. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012. Janssen also currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases."[98]

259. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

#### 4. Falsehood #4: Opioid Withdrawal Can Be Avoided By Tapering

260. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient's dose to avoid the adverse effects of withdrawal.

[98] Howard Heit, MD, FACP, FASAM, & Douglas Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids, (last accessed July 16, 2018).

Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

261. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

262. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

263. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

264. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

### 5. Falsehood #5: Opioid Doses Can Be Increased Without Limit or Greater Risks

265. In materials they produced, sponsored or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

266. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. d

267. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

268. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

269. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[99]

[99] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma

270. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

271. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased . . . You won't 'run out' of pain relief."

272. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

**6. Falsehood #6: Long-term Opioid Use Improves Functioning**

273. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

274. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

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L.P., https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafet%20y/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf, (last modified Nov. 2010).

275. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine…We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[100]

276. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[101]

277. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

278. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

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[100] *Pain Killer*, *supra* n. 79, at 281.

[101] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

279. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

280. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

281. In addition, Janssen's *Let's Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

282. Endo's NIPC website, *Painknowledge.com*, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

283. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

284. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[102]

285. The Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[103] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[104]

286. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that Opioids for chronic

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[102] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporate-responsibility/responsible-use, (last accessed July 16, 2018).

[103] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[104] CDC Guideline at 20.

pain may actually worsen pain and functioning . . .”[105] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

287. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”[106] According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”[107]

288. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”[108] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[109] Another study demonstrated that injured

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[105] Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).
[106] CDC Guideline at 2, 18.
[107] Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (AprilApr. 21, 2016), doi: 10.1056/NEJMp1515917, http://www.nejm.org/doi/full/10.1056/NEJMp1515917.
[108] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747
[109] Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[110] Yet, Marketing Defendants have not acknowledged, retracted, or corrected their false statements.

### 7. Falsehood #7: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

289. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs ("NSAIDs").

290. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[111] hormonal dysfunction;[112] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[113] neonatal abstinence syndrome (when an infant exposed to opioids

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[110] Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, https://www.ncbi.nlm.nih.gov/pubmed/18197107.

[111] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[112] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), https://www.ncbi.nlm.nih.gov/pubmed/14622741.

[113] *See* Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi: 10.1093/eurpub/cku120, https://www.ncbi.nlm.nih.gov/pubmed/25085470.

prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids.

291. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.[114]

292. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

293. Endo's NIPC website, *Painknowledge.org*, contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

294. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[115] The article asserted:

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[114] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), https://www.ncbi.nlm.nih.gov/pubmed/14704592.

[115] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf, (link no longer available).

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[116]

295. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

296. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

297. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[117]

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[116] *Id.*

[117] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). "For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady.." *See also*, J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

### 8. Falsehood #8: OxyContin Provides Twelve Hours of Pain Relief

298. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

299. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

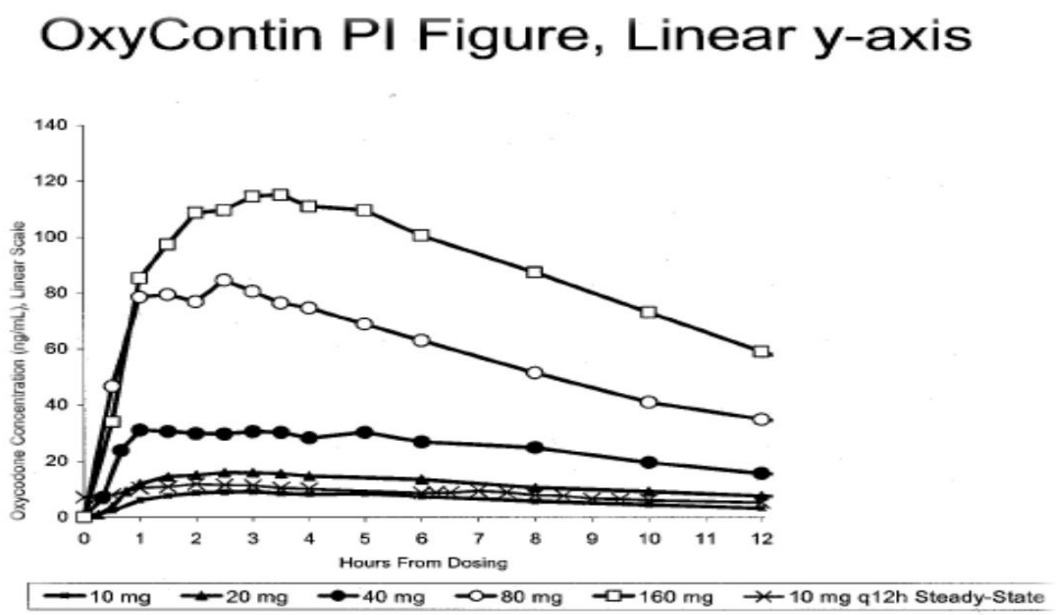



Figure 1

300. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for

the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

301. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

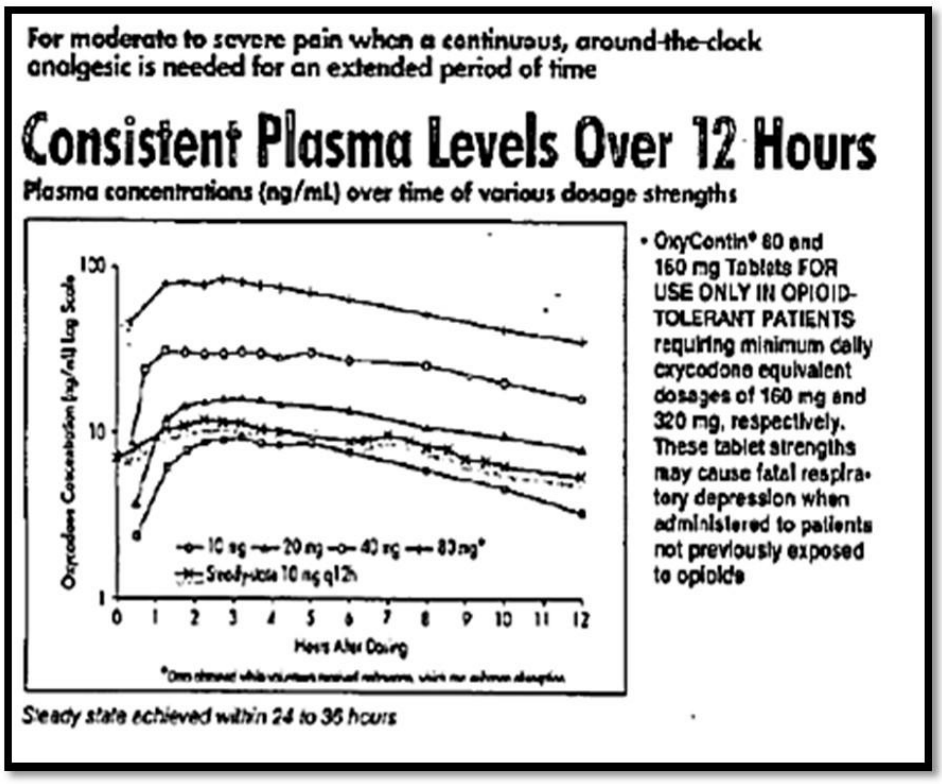
302. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[118] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

303. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

304. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the

[118] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

previous page. However, this version of the chart deceptively minimized the rate of end-of- dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y- axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:




305. Purdue's 12-hour messaging was key to its competitive advantage over short- acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February

2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[119]

306. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[120]

307. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

308. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

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[119] Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/oxycontin-launch-1995/.

[120] CDC Guideline at 16.

309. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses."[121] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud. NOW!!"[122]

310. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

### 9. Falsehood #9: New Formulations of Certain Opioids Successfully Deter Abuse

311. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

312. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of

[121] Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/
[122] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

**a. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER**

313. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

314. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

315. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. asserted or suggested that its ADF opioids are non-addictive or less addictive,

d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and

e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

316. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

317. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

318. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)". In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

319. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

320. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

321. Websites and message boards used by drug abusers, such as *bluelight.org* and *reddit.com*, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

322. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

323. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[123] In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

324. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

[123] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

**b. Endo's Deceptive Marketing of Reformulated Opana ER**

325. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

326. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

327. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent.

328. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

329. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[124] The FDA responded that:

[124] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's

"Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[125]

330. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[126]

331. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[127]

332. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

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Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[125] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[126] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

[127] CP, FDA Docket 2012-8-0895, at 2.

333. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[128] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

334. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

335. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

336. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." For example, a June 14, 2012 Endo press release announced, "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

[128] Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014)), https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/.

337. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers. The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

338. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

339. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.[129] Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.[130] However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

**c. Other Marketing Defendants' Misrepresentations Regarding Abuse Deterrence**

340. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO

[129] Press Release, FDA, FDA requests removal of Opana ER for risks related to abuse, (June 8, 2017), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

[130] Press Release, Endo International plc, Endo Provides Update on Opana ER, (July 6, 2017), *available at* https://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html.

may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[131] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."

341. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[132] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[133]

342. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

343. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants' misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

### B. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

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[131] Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), *available at* http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

[132] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

[133] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/

344. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

345. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs.

### C. The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use

346. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.[134] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

347. "Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient

[134] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (FebruaryFeb. 12, 2018), https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at p. 3.

treatment, raising disease awareness, and educating the public.'"[135] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[136] Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[137] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of Office opioids policy,"[138] found that the Marketing Defendants made millions of dollars' worth of contributions to various Front Groups.[139]

348. The Marketing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[140]

349. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[141] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding."[142]

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[135] *Id.* at p. 2.
[136] *Id.*
[137] *Id.* at p. 1.
[138] *Id.*
[139] *Id.* at p. 3.
[140] *Id.* at p. 10.
[141] *Id.* at 12-15.
[142] *Id.* at 12.

350. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other deceptively to promote the use of opioids for the treatment of chronic pain.

**1. American Pain Foundation**

351. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

352. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

353. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.org*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it

as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

354. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "*Partners Against Pain*" and Janssen's "*Let's Talk Pain.*" Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share its business interests.

355. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

356. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason.

357. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's lack of independence in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that

worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions.

358. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

**2. American Academy of Pain Medicine and the American Pain Society**

359. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[143] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

360. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

361. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and

[143] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), a*vailable at* http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (last accessed August 1, 2018).

can be managed."[144]

362. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

363. More specifically, Purdue paid $725,584.95 from 2012-2017 to AAPM.[145] Janssen paid $83,975 from 2012-2017 to AAPM.[146] Insys paid $57,750 from 2012-2017 to AAPM.[147] Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

364. As to APS, Purdue paid $542,259.52 from 2012-2017.[148] Janssen paid $88,500 from 2012-2017.[149] Insys paid $22,965 from 2012-2017.[150] Mylan paid $20,250 from 2012-2017.[151]

365. AAPM describes its annual meeting as an "exclusive venue" for offering Continuing Medical Education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

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[144] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* http://www.medscape.org/viewarticle/500829.

[145] *Id.*

[146] *Fueling an Epidemic Part Two.*

[147] *Id.*

[148] *Fueling an Epidemic Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocary Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, https://www.hsdl.org/?abstract&did=808171 (last accessed August 1, 2018) (hereinafter referred to as "*Fueling an Epidemic Part Two*")

[149] *Id.*

[150] *Id.*

[151] *Id.*

366. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

367. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011.

368. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

369. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

370. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

371. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[152]

372. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

373. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

### 3. FSMB

374. The Federation of State Medical Boards (FSMB) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

375. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

376. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

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[152] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, (March 15, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm, (hereinafter "2016 CDC Guideline").

377. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Pima County.

378. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid $100,000 for printing and distribution of FSMB's Guidelines.[153]

379. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.[154] The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.[155]

380. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were

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[153] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.

[154] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.

[155] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

381. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB – this is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.[156]

382. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB $822,400.06 over 8 years.[157] Cephalon paid FSMB $180,000 over 3-year period 2007-2008 and 2011.[158] Endo paid FSMB $371,620 over a 5-year period.[159] Mallinckrodt paid FSMB $100,000 in 2011.[160]

**4. The Alliance for Patient Access**

383. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[161] It is run by Woodberry Associates LLC, a lobbying firm that was also established in

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[156] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.

[157] Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html.

[158] *Id.*

[159] *Id.*

[160] *Id.*

[161] The Alliance for Patient Access, *About AfPA*, http://allianceforpatientaccess.org/about-afpa/#membership (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

2006.[162] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

384. APA's board members have also directly received substantial funding from pharmaceutical companies.[163] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[164] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

385. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[165] Among other things, the white

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[162] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ ("Jaklevic, *Non-profit Alliance for Patient Access*").

[163] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, *available at* https://projects.propublica.org/docdollars/.

[164] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[165] Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While*

paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> ***
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> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[166]

386. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board-certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.167

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*Curbing Abuse*, (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

[166] *Id.* at 4-5 (footnote omitted).

[167] *Id.* at 5-6.

387. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[168]

388. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[169]

389. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA's agenda.[170]

390. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act").[171] The AAPM is also a

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[168] *Id.* at 6.
[169] *Id.* at 7.
[170] Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n. 195.
[171] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[172] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the courts.[173] The law passed both Houses of Congress and was signed into law in 2016.

**5. The U.S. Pain Foundation**

391. The U.S. Pain Foundation (USPF) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[174] The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[175] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

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[172] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").

[173] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.

[174] *Fueling an Epidemic*, at p. 4.

[175] *Id.* at 12; U.S. Pain Foundation, *Transparency*, https://uspainfoundation.org/transparency/. (last accessed on August 1, 2018).

[175] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).

392. More specifically, Purdue paid $359,300 from 2012-2017 to the USPF.[176] Janssen paid $41,500 from 2012-2017.[177] Insys paid $2,500,000 from 2012-2017.[178]

**6. American Geriatrics Society**

393. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,[179] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[180] AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

394. More specifically, Purdue paid $11,785 from 2012-2017[181] and provided $40,000 in "corporate roundtable dues" to AGS's Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.[182]

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[176] *Id.*
[177] *Id.*
[178] *Id.*
[179] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).
[180] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.
[181] *Fueling an Epidemic Part Two*.
[182] Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

395. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[183] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

396. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

397. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.[184]

398. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

399. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

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[183] 2009 AGS Guidelines, at 1342.

[184] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.

### 7. American Chronic Pain Association

400. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

401. Contributions to the ACPA from the Manufacturing Defendants include: Purdue paid $312,470 from 2012-2017.[185] Janssen paid $50,000 from 2012-2017.[186] Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than $140,000 from opioid manufacturers, including Endo.

## D. The Marketing Defendants Deceptively Paid Key Opinion Leaders to Promote Opioid Use

402. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine and Dr. Scott Fishman.

403. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

404. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic

[185] *Fueling an Epidemic Part Two*.
[186] *Id.*

pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

405. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

406. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

407. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants kept these KOLs well-funded to enable them to push the Marketing Defendants' deceptive message out to the medical community.

408. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

409. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly

disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

**1. Dr. Russell Portenoy**

410. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[187]

411. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[188]

(emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but

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[187] Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550.

[188] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

the most desperate cases of chronic nonmalignant pain."[189]

412. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious- like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[190]

413. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[191]

414. Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

415. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[192] Dr. Portenoy has now admitted that he minimized the risks of opioids,[193] and that he

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[189] *Id.*
[190] *Dreamland* at 314.
[191] *Id.* at 136.
[192] *See, e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).
[193] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter "Gounder, *Who Is Responsible*").

"gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[194] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."[195]

416. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[196]

417. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[197]

**2. Dr. Lynn Webster**

418. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic

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[194] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[195] *Id.*

[196] Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[197] *Pain Killer*, *supra* n. 79, at 277.

opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

419. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors at Tucson Medical Center.

420. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

421. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that

FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

422. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

### 3. Dr. Perry Fine

423. Dr. Perry Fine's ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[198]

424. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

425. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from Johnson

[198] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true.

& Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.[199]

426. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[200]

427. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[201] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain."[202] The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence-

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[199] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

[200] Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[201] Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

[202] *Id.*

and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[203]

428. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[204]

429. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[205] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*."[206] The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[207]

#### 4. Dr. Scott Fishman

430. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below,

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[203] *Id.*
[204] *Id.*
[205] Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI
[206] *Id.*
[207] *Id.*

he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non- cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[208]

431. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

432. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[209]

433. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins."[210]

434. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a

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[208] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

[209] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

[210] *Id.*

'chemical coper' and an addict."[211] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

### E. The Marketing Defendants Also Spread Their Misleading Messages to Reputable Organizations

435. The Manufacturing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations ("The Joint Commission") in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation's oldest and largest standards-setting and accrediting body in health care.[212] Only hospitals that have been accredited by the Joint Commission can receive payments from Medicare and Medicaid.[213]

436. In 2000, Purdue sponsored a book through The Joint Commission which claimed "there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[214] It also called doctors' concerns about addiction side effects "inaccurate and exaggerated."[215] Dr. David W. Baker, The Joint Commission's executive vice president for health care quality evaluation, has acknowledged that "The Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."[216]

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[211] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).
[212] Joint Commission, *FAQ Page*, *available at* https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274 (last accessed August 1, 2018).
[213] U.S. S. Comm. on Homeland Security and Government Affairs Field Hearing, "Border Security and America's Heroin Epidemic: The Impact of the Trafficking and Abuse of Heroin and Prescription Opioids in Wisconsin," at 6 (Apr. 15, 2016) (Testimony of Time Westlake, M.D., Vice Chairman, State of Wisconsin Medical Examining Board Controlled Substances Committee Chairman) ("Westlake testimony").
[214] Sonia Moghe, *Opioid history: From 'wonder drug' to abuse epidemic*, CNN (Oct. 13, 2016), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/.
[215] *Id.*
[216] *Id.*

437. In 2001, due to the influence of the Marketing Defendants, The Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[217]) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

438. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals); and, emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

439. As a result of the Marketing Defendants' efforts to manipulate the standard of care, many hospitals, including Plaintiff, risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States has been able to accomplish.[218] However, during its routine Joint Commission survey, The Joint Commission found that the hospital was not adequately documenting follow up questions after prescribing pain medications to patients.[219] As a result, the hospital was given only one quarter to bring their compliance up to 90%.[220] They could not, and as a result their Joint Commission accreditation was at risk for the entire hospital.[221] Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital

[217] Currently funded by Johnson & Johnson, Purdue and Teva, among others.
[218] Westlake testimony, at 6.
[219] *Id.*
[220] *Id.*
[221] *Id.*

resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.[222]

440. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' marketing campaigns could not be undone. Dr. Baker explains that "the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later."

### F. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

441. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

442. One way the Marketing Defendants aggressively distributed their false message was through countless of CME programs.

443. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

444. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of

[222] *Id.*

expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

445. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

446. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

447. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain*: *Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway."[223] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.[224] Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

448. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-

[223] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last accessed August 1, 2018).
[224] *Id.*

cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

449. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

450. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

451. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs create; stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urged that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[225]

452. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

453. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers' views on opioids and

[225] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

### G. The Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers

454. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

455. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[226] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[227] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient- focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

### H. The Marketing Defendants Used "Unbranded" Advertising To Promote Opioid Use For Chronic Pain Without FDA Review

[226] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

[227] *Id.*

456. The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

457. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

## I. The Marketing Defendants Funded, Edited And Distributed Publications That Supported Their Misrepresentations

458. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

459. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

460. The Marketing Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants' marketing departments.

461. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

462. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

463. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[228] published in the nationally circulated journal Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-

[228] Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

cancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[229]

### J. The Marketing Defendants Used "Detailers" To Directly Disseminate Their Misrepresentations To Prescribers

464. The Marketing Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

465. Each Marketing Defendant promoted opioids through sales representatives (also called "detailers") and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

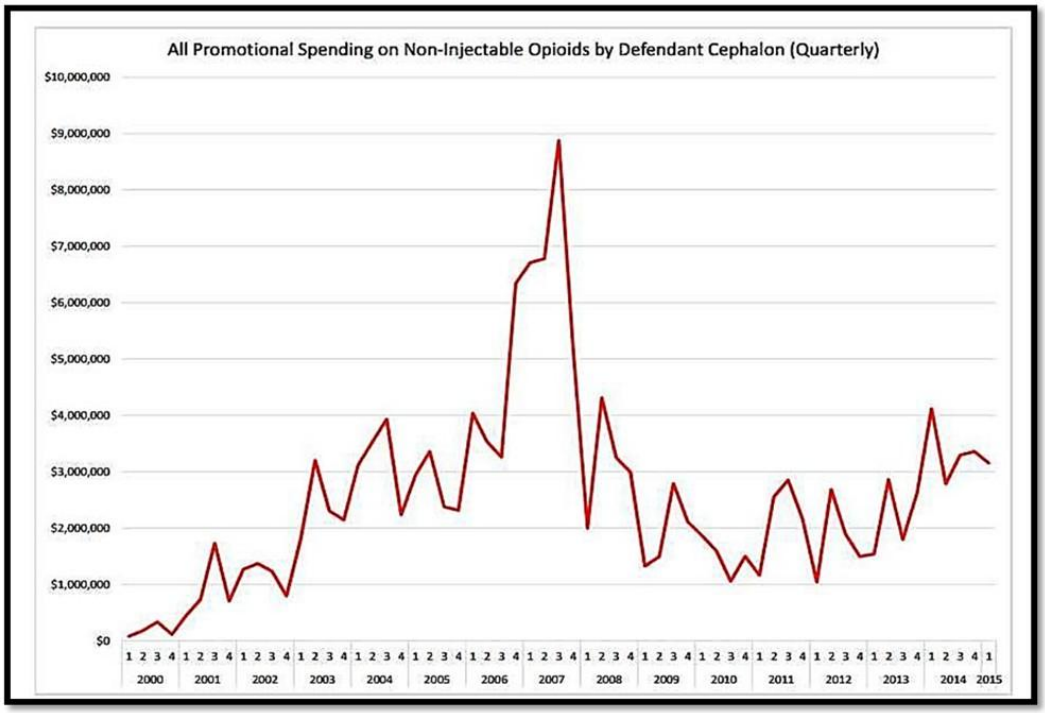
466. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and

[229] *Id.*

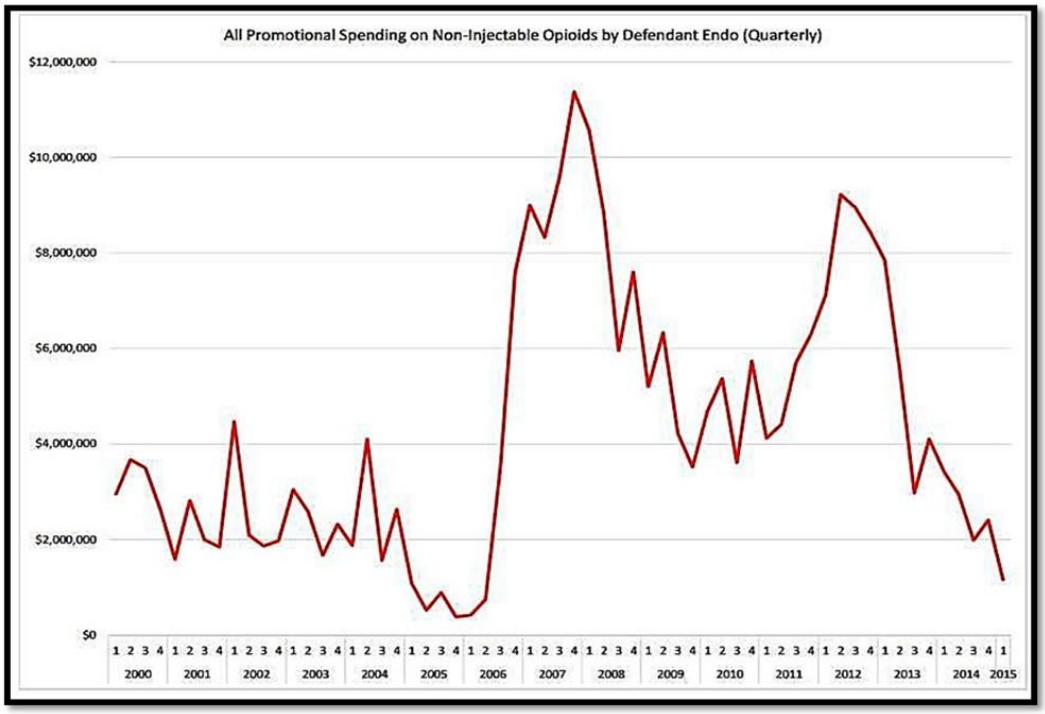
tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

467. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

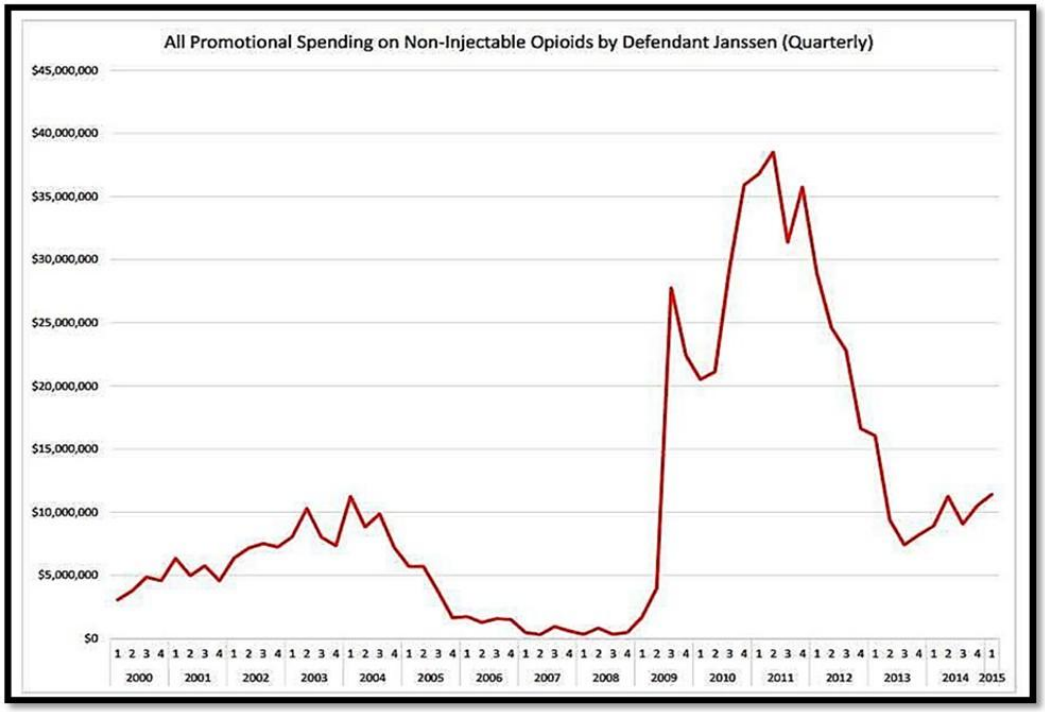
468. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:



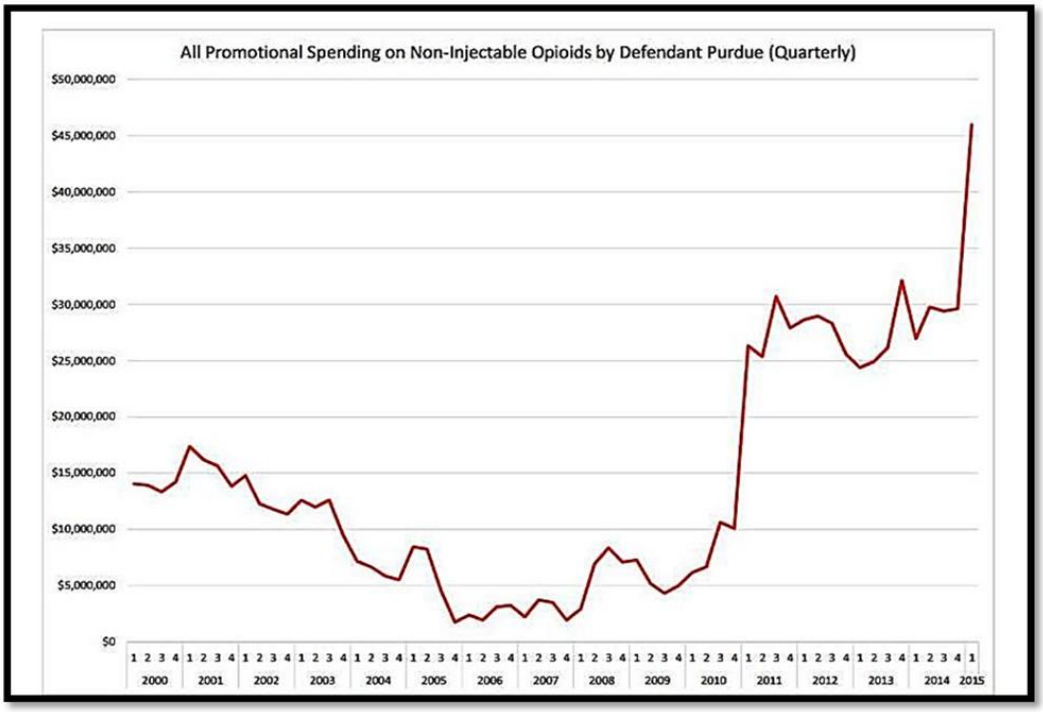

469. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than$38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):




470. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



471. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:




472. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

### K. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

473. In addition to making sales calls, the Marketing Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings served three purposes: they provided an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing Defendants graded their speakers, and future opportunities were based on speaking

performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

474. As detailed below, Insys paid prescribers for *fake* speakers programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program. Insys used speakers programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

**L. The Marketing Defendants Targeted Vulnerable Populations**

475. The Marketing Defendants specifically targeted their marketing toward the elderly, who often suffer from chronic pain.

476. The Marketing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[230] Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients. The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[231]

477. Opioid prescriptions have dramatically increased for the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

[230] 2016 CDC Guideline, *supra* n. 185.
[231] *Id.* at 27.

### M. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

478. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

479. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a REMS (Risk Evaluation and Medication Strategy) for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of the REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[232] Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

480. Since its launch, Subsys has been an extremely expensive medication, and has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

481. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . ."[233]

[232] Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*, Dec. 29, 2011.
[233] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members'

482. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center ("IRC"), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

483. Subsys has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

484. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

485. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded representatives more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[234]

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Office, Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (Sept. 6, 2017), https://www.hsdl.org/?view&did=803959.

[234] *Id.*

486. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."[235] It was a pay-to-prescribe program.

487. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

488. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017 one of the doctors was sentenced to 20 years in prison.

489. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately $1,000 per event; however,

[235] Roddy Boyd, *Insys Therapeutics and the New "Killing It"*, Southern Investigative Reporting Foundation, THE INVESTIGATOR (April 24, 2015), http://sirf-online.org/2015/04/24/the-new-killing-it/.

she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

490. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

491. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from $700 to $5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

492. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: "Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis."[236] The DEA Special Agent

[236] Press Release, DOJ, U.S. Attorney's Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

in Charge further explained that: "Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."[237]

493. In August of 2017, the Attorney General for Arizona filed suit against Insys for similar deceptive and illegal practices. The Complaint alleged that Insys provided insurers and pharmacy benefit managers ("PBMs") with false and misleading information in order to obtain prior authorization for patients' Subsys prescriptions. In addition, the Complaint alleged that Insys provided deceptive information to healthcare professionals in order to deceive them into believing the FDA had approved Subsys for more uses than the FDA had actually approved. The Complaint also alleges that as a result of the sham services and "speaker fees" offered by Insys, the company secured a total of $51.87 million dollars in gross sales in the state of Arizona between March 2012 and April 2017.

## IX. THE MARKETING DEFENDANTS' SCHEME SUCCEEDED, CREATING A PUBLIC HEALTH EPIDEMIC

### A. The Marketing Defendants' Dramatically Expanded Opioid Prescribing and Use

494. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

495. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and

[237] *Id.*

targeting our marketing efforts to pain specialists."[238] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[239] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[240]

496. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. Their purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

497. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[241] The effects of sales calls on prescribers' behavior is well

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[238] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[239] Carreyrou, *Narcotic Lollipop*.
[240] *Id.*

[241] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label

documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

498. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[242] These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

499. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

### B. The Marketing Defendants' Deception In Expanding Their Market Created And Fueled The Opioid Epidemic.

500. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[243] It has been

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use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[242] CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, https://www.ncbi.nlm.nih.gov/pubmed/25485657.

[243] Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, https://www.cdhs.udel.edu/content-sub-

estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

501. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[244]

502. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

## X. THE MARKETING DEFENDANTS' MARKETING SCHEME MISREPRESENTED THE RISKS AND BENEFITS OF OPIOIDS

### A. The Marketing Defendants Targeted Susceptible Prescribers

503. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants' misrepresentations.

504. "From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau. It is well documented that this type of

site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf.

[244] *See* Califf et al., *supra* n. 16.

pharmaceutical company symposium influences physicians' prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."[245]

## XI. THE MARKETING DEFENDANTS MADE MATERIALLY DECEPTIVE STATEMENTS AND CONCEALED MATERIAL FACTS

505. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint**.**

### A. Purdue

506. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

[245] Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. Journal of Public Health 2 (February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting the elderly by assisting in the distribution of guidelines that

contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

o. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

p. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

q. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

507. More specifically, Defendant Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.[246]

b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that "fewer than one per cent" of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[247]

[246] Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

[247] *Id.*

c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. "If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off," Kolodny said. "It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks."[248]

d. "Purdue had a speakers' bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn't. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company."[249]

e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid $40 million in bonuses to its sales representatives.[250]

f. Purdue claimed that the risk of addiction from OxyContin was

[248] *Id.*
[249] *Id.*
[250] *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

extremely small and trained its sales representatives to carry the message that the risk of addiction was "less than one percent," while knowing that there was no empirical support for that statement.

g. By 2003, the Drug Enforcement Administration had found that Purdue's "aggressive methods" had "very much exacerbated OxyContin's widespread abuse." Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had "deliberately minimized" the risks associated with the drug.[251]

508. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

| | |
|---|---|
| Academy of Integrative Pain Management | $1,091,024.86 |
| American Academy of Pain Management | $725,584.95 |
| ACS Cancer Action Network | $168,500.00[252] |
| American Chronic Pain Association | $312,470.00 |
| American Geriatrics Society | $11,785.00[253] |
| American Pain Foundation | $25,000 |
| American Pain Society | $542,259.52 |
| American Society of Pain Educators | $30,000 |
| American Society of Pain Management Nursing | $242,535.00 |
| The Center for Practical Bioethics | $145,095.00 |

[251] *The Family that Built an Empire of Pain*, https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

[252] Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

[253] The AGS reported that Purdue also provided $40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

| | |
|---|---|
| U.S. Pain Foundation | $359,300.00 |
| Washington Legal Foundation | $500,000.00 |
| TOTAL | $4,153,554.33 |

**B. Endo**

509. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b.

c. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

d. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

e. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

f. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

g. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

h. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

i. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

j. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

k. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

l. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

m. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

n. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

o. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

**C. <u>Janssen</u>**

510. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat

chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

m. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

**D. <u>Depomed</u>**

511. Depomed has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

a. Promoting the usage of Lazanda with patients not suffering from cancer;

b. Endorsing, supporting, and pressuring its sales representative to target pain

management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;

c. Discouragement of sales representatives from targeting physicians treating cancer patients in contradiction to the FDA approved warning indicating that Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;"

d. Training of sales representatives on how to deal with pushback from physicians;

e. Promotion of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug's addictive nature;

f. Promoting its drugs as a safer alternative than other opioids;

g. Telling investors that Depomed is safe. August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a];though not in the label, there's a very low abuse profile and side effect rate;"

**E. Cephalon**

512. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent

rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

**F. Actavis**

513. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term

treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

**G. Mallinckrodt**

514. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating and promoting publications that misrepresented and trivialized the risks of addiction;

b. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

c. Making deceptive statements about pseudoaddiction.

**H. Insys**

515. Defendant Insys made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the appropriateness of the use of Subsys to treat neck and back and other chronic pain conditions without disclosing the lack of approval and lack of evidence for such uses;

b. Implementing a kickback scheme wherein providers were incentivized to prescribe Subsys in exchange for payment as speakers in fake speakers programs; and

c. Obtaining authorization for approval of payor reimbursement for Subsys through a deceptive prior authorization program that falsified patient medical

histories, falsely claimed that patients had cancer, and provided misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

## XII. MARKETING DEFENDANTS' PRIOR BAD ACTS

516. Defendants have long known about the dangers of their opioid products, and the alarming quantities in which they were pouring into communities all across the country, because they have been sued, fined, and criminally convicted for failing to mitigate these problems.

517. For example, in 2007 Purdue settled criminal and civil charges against it for "misbranding" OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly $635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.[254]

518. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana,[255]the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[256]

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[254] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[255] Press Release, State of Ind. Health Dep't, HIV Outbreak in Southeastern Indiana, (Feb. 25, 2015), http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489.

[256] Jen Christensen, *FDA wants Opioid Painkiller Pulled off Market*, CNN (June 8, 2017), https://www.cnn.com/2017/06/08/health/fda-opioid-opana-er-bn/index.html; Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

519. In 2017, The Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.

## XIII. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

520. The Distributor Defendants owe a duty under, *inter alia*, Arizona common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

521. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

522. Each Distributor Defendant repeatedly and purposefully breached its duties under Arizona law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

523. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

524. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

525. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the

damages alleged herein.

## XIV. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

526. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

527. Defendants are all required to register as either manufacturers or distributors pursuant to A.R.S. § 36-2522 (A); A.A.C. R4-23-604; A.A.C. R4-26-605.

528. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

529. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[257] Patients receiving

[257] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[258]

**A. All Defendants Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders**

530. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Each Defendant was required to register with the State of Arizona. A.R.S. § 36-2522 (A); A.A.C. R4-23-604; A.A.C. R4-26-605. Each Defendant is a "registrant" of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Each Defendant has an affirmative duty under to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs, Arizona law requires that "registrants" of Schedule II drugs, including opioids, must "maintain effective controls against the diversion of controlled substances or precursor chemicals to unauthorized persons or entities." A.R.S. § 32-1901.01. S*ee also* A.A.C. R4-23-604; A.A.C. R4-23-605; A.A.C. R4-23-607.

531. Arizona statutes and regulations impose non-delegable duties upon registrants to maintain effective controls against diversion, and design and operate a system to disclose to the registrant suspicious orders of controlled substances. Arizona common law (1) imposes duties of reasonable care upon persons who market and distribute opioids, both to (a) maintain effective controls against diversion, and (b) to avoid engaging in deceptive or misleading marketing practices, and (2) imposes liability under the common law of nuisance against persons who negligently, recklessly and/or intentionally cause the distribution of narcotics through unauthorized channels and/or to persons to whom they should not be distributed.

532. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the

[258] *Id.*

order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

533. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels

534. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[259]

535. "Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and

[259] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

responsibilities."[260]

536. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

[260] Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter Brief for HDMA and NACDS). The Healthcare Distribution Mgmt. Ass'n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA) —is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/%20about/mission/ (last accessed Aug. 1, 2018).

537. The Distributor Defendants have publicly acknowledged that wholesale distributors are a key component in the distribution chain and that that they are responsible for reporting suspicious orders.[261]

538. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[262]

539. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with that it "had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders…"

540. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific

[261] *See* Brief for HDMA and NACDS, *supra* n. 297, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[262] *See* Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep't of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter Brief of HDMA in Support of Cardinal).

drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[263]

541. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

542. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

543. Each Distributor Defendant owes a duty under Arizona law to investigate and refuse suspicious orders of prescription opioids.

544. Each Distributor Defendant owes a duty under Arizona law to report suspicious orders of prescription opioids.

545. Each Distributor Defendant owes a duty under Arizona law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

546. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by others.

547. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs associated with the treatment of these conditions and related health consequences caused by opioid abuse.

548. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For

[263] Healthcare Distribution Mgmt. Ass'n (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

549. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes; and thus, to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

550. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance ("HDA") includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to "downstream registrants", meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

551. A dramatic example of the use of prescription information provided by IMS Health took place in Congressional testimony:

> Mr. Greenwood: Well, why do you want that [IMS Health] information then?
>
> Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.
>
> Mr. Greenwood. And so, the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent "X"' number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?
>
> Mr. Friedman: Sure.[264]

552. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The Defendants negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

### 1. Pain Care Forum

553. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in

[264] *Oxycontin: Its Use and Abuse*: *Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives*, 107th Cong. 54 (2001) (statements of James C. Greenwood, Member, Committee on Energy and Commerce and Michael Friedman, Executive Vice President and COO of Purdue Pharma, L.P.), available at https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

554. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[265] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[266]

555. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.[267] In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[268] The Distributor Defendants participated directly in the PCF as well.

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[265] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic (emphasis added).

[266] *Id.*

[267] *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[268] *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), https://www.healthcaredistribution.org/about/executive-committee%20.

**2. HDA**

556. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[269] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthening . . . alliances."[270]

557. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[271] The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

558. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[272] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

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[269] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Aug. 1, 2018).

[270] *Id.*

[271] *Id.*

[272] *Id.*

559. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

560. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

561. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[273] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[274] The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.[275]

562. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical

[273] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and- leadership-conference/blc-for-manufacturers (last accessed Aug. 1, 2018, and no longer available).

[274] *Id.*

[275] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last accessed Aug. 1, 2018).

distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

563. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and

invoices.[276] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" The Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

564. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

565. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

566. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the Fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

567. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their legal duties with respect to the distribution of controlled substances. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is

[276] *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

"difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

568. The Defendants' scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids.

569. The Defendants worked together to control the flow of information and to influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

570. The Defendants also had obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

571. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be revealed. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency.

572. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

### B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

573. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled

substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[277]

574. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

### C. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

575. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

576. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

577. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

[277] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

578. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

579. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

580. The Distributor Defendants developed "know your customer" questionnaires and files. This information was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[278] The "know your customer"

[278] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

581. Defendants purchased nationwide, regional, state, and local prescriber-and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[279]

582. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[280]

583. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[281]

584. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled

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[279] A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[280] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

[281] *Sorrell v. IMS Health Inc.*, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

substances.[282] Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

585. Defendants refused to identify, investigate and report suspicious orders when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite several decisions against the Distributor Defendants.

586. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

587. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of

[282] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.[283] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[284]

588. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[285] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[286] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

589. A Kadian prescriber deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."

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[283] *Pain Killer*, *supra* n. 79, at 298-300.
[284] *Id.*
[285] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[286] *Id.*

(p. 1-2). The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

590. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

591. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

592. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

593. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[287]

[287] *Pain Killer*, *supra* n. 79, at 179.

594. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

595. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

596. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

### D. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

597. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids in disregard of their legal duties to control the supply, prevent diversion, report and take steps to halt suspicious orders.

598. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

599. In 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

600. On December 23, 2016, Cardinal agreed to pay the United States $44 million to resolve allegations that it violated federal regulations and statutes in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone.

601. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of consumer credit and protection laws, antitrust laws and, the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal and another distributor, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal settled for $20 million.

602. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

603. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a

valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

604. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

605. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

### E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

606. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

607. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

608. The Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from

being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

609. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

610. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:[288]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

611. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the

[288] Brief for HDMA and NACDS, *supra* n. 297, 2016 WL 1321983, at *3-4, *25.

Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

612. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."

613. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement.[289]

614. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid epidemic.

615. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[290] Purdue's statement on "Opioids Corporate Responsibility" likewise

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[289] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[290] Purdue website, *Opioids With Abuse-Deterrent Properties*, \ http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last accessed Aug. 1, 2018).

states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[291]

616. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

617. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

**F. The Distributor Defendants Breached Their Duties**

618. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

619. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[292]

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[291] *Id.*

[292] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

620. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

621. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

622. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

623. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

624. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities of suspicious orders when discovered, in violation of their duties under Arizona law.

625. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[293]

626. The laws at issue here concerning the sale and distribution of controlled substances are also Arizona public safety laws.

627. The Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under State law.

628. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by Arizona law which are required to legally acquire and maintain a license to distribute prescription opiates.

[293] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

629. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

630. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

**1. Cardinal**

631. To date, Cardinal has paid a total of $98 million in fines and other amounts involving multiple actions relating to its improper management and distribution of opioids to pharmacies across the United States.

632. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses[294] around the United States (the "2008 Cardinal Settlement Agreement").[295] These allegations included failing to report thousands of suspicious

[294] Including its Lakeland, Florida facility. https://www.dea.gov/pubs/pressrel/pr100608.html. In 2012, Cardinal described the Lakeland facility as shipping "an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida." *Cardinal Health, Inc. v. Eric Holder, Jr., Att'y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

[295] Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is *available at* https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att'y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.[296]

633. In 2012, Cardinal reached another settlement relating to its failure to "conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels" resulting in systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement").[297] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.[298]

634. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.[299]

635. In December 2016, Cardinal again settled charges that it had failed to prevent diversion of oxycodone for illegal purposes, this time for $44 million (the "2016 Cardinal Settlement Agreement").[300] The settlement covered DEA allegations that Cardinal had failed to

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[296] *Id.*

[297] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.

[298] *Id.*

[299] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018).

[300] U.S. Att'y Office, Dist. of Md., *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

report suspicious orders across Washington, Maryland, New York, and Florida.[301] The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.[302] The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.[303]

**2. AmerisourceBergen**

636. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

637. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[304] Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."[305]

638. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[306]

**G. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties**

639. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under Arizona law and have wrongfully and repeatedly disavowed those duties

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[301] *Id.*
[302] *Id.*
[303] *Id.*
[304] Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), https://www.dea.gov/divisions/mia/2007/mia042407p.html.
[305] *Id.*
[306] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), *available at* https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

640. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores ("NACDS") submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing. The HDA argued that distributors did not have a responsibility to investigate suspicious orders or halt them before they could be filled. The Court, in that proceeding, held otherwise.

641. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[307]

642. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[308]

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[307] *See* Brief of HDMA in Support of Cardinal, *supra* n. 306, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

[308] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-

643. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

644. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[309] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

645. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts.

646. Meanwhile, the opioid epidemic rages unabated in the United States and Arizona.

647. The epidemic still rages because the fines and suspensions imposed do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They

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d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

[309] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

hold multiple registration numbers and when one facility is suspended, they simply ship from another facility.

648. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's allegations of Defendants' unlawful acts below.

649. The Distributor Defendants have abandoned their duties imposed under Arizona law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

## XV. THE MARKETING DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

650. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Marketing Defendants under Arizona law. Like the Distributor Defendants, the Marketing Defendants were required to register with the Arizona Board of Pharmacy to manufacture Schedule II controlled substances, like prescription opioids. A.R.S. § 13-3401; A.R.S. § 32-1927.03. A requirement of such registration is the "to maintain effective controls against the diversion of controlled substances or precursor chemicals to unauthorized persons or entities." A.R.S. § 32-1901.01(A)(26). Defendants failed to maintain effective controls as required under § 32-1901.01(A)(26), and to comply with the other requirements imposed by Arizona's Uniform Controlled Substances Act.

651. Like the Distributor Defendants, the Marketing Defendants breached these duties.

652. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the

manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Marketing Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

653. Federal and Arizona statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to design and operate a system to disclose . . . suspicious orders of controlled substances and to maintain effective controls against diversion.

654. The Department of Justice has recently confirmed the suspicious order obligations imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[310]

655. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers Mallinckrodt failed to distribute these controlled substances in a manner authorized by its registration and failed to operate an effective suspicious order monitoring system and to report suspicious orders.

656. Mallinckrodt acknowledged that "[a]s part of [its] business model Mallinckrodt collects transaction information, referred to as chargeback data, from [its] direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it

[310] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[311]

657. The same duties imposed by law on Mallinckrodt were imposed upon all Marketing Defendants.

658. That the same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

659. Through, *inter alia*, the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

660. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by Arizona law.

661. The Marketing Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

662. The Marketing Defendants have misrepresented their compliance with Arizona law.

663. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and which were a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's allegations of Defendants' unlawful acts below.

664. The Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

**A. <u>Defendants' Unlawful Conduct And Breaches Of Legal Duties Caused The Harm Alleged Herein And Substantial Damages</u>**

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[311] *Id.*

665. As the Marketing Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

666. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[312]

667. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[313]

668. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[314]

669. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[315]

670. One doctor, for example in Ohio, was convicted of illegally distributing some 30,000 tablets of oxycodone, OxyContin, and Opana. In connection with sentencing, the U.S. Attorney explained that its enforcement efforts reflected that "[o]ur region is awash in opioids that have brought heartbreak and suffering to countless families." Henry Schein delivered opioids directly to the office of this doctor, whom the Northern District of Ohio court has described as "selling 30,000 doses of poison into the community."[316] In a separate civil suit, the same prescriber reached a consent judgment in a civil suit alleging that he was purchasing hydrocodone/APAP

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[312] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), DOI: 10.1056/NEJMsa1406143, http://www.nejm.org/doi/full/10.1056/NEJMsa1406143.

[313] *See* Volkow & McLellan, *supra* n. 67.

[314] *See* Califf et al., *supra* n. 16.

[315] *See* Press Release, Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* n. 61.

[316] Eric Heisig, *Former Akron-Area Doctor Sentenced to 63 Months in Prison for Doling Out Painkillers*, Cleveland.com (Mar. 16, 2015), https://www.cleveland.com/court-justice/index.ssf/2015/03/former_akron-area_doctor_sente.html.

tablets (hydrocodone and acetaminophen), from Henry Schein on as many as fourteen separate dates within a one-year period, and, subsequently dispensed 11,500 hydrocodone tablets without maintaining purchase and dispensing records as required by law.

671. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization and death that goes hand in hand with Defendants' increased distribution of opioids.

672. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

673. Defendants repeatedly and purposefully breached their duties under federal and Arizona law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals, and other health care providers.

674. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiff.

675. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief.

## XVI. CONSPIRACY ALLEGATIONS

### A. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

#### 1. Conspiracy Among Marketing Defendants

676. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management

of pain in order to mislead physicians, patients, health care providers, such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

677. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

678. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

679. The Marketing Defendants knew that none of these propositions are true.

680. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

681. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids, and to

hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

682. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

683. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants

684. The most unnerving tactic utilized by the Marketing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

685. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

686. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

687. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite the letter's obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

688. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers, such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particularly, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy…

By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

**2. <u>Conspiracy Among All Defendants</u>**

689. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

690. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

691. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

692. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from Defendants' facilities.

693. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the government's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency.

694. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

**B. Facts Pertaining to Punitive Damages**

695. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

696. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this

knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion.

697. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country and economic loss to families, communities, hospitals and health care providers, across the country.

### 1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

698. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions, as described more fully below.

#### a. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

699. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

700. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that

Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

701. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

**b. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon From Falsely Marketing Actiq For Off-label Uses**

702. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

703. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

**c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

704. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied

Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

705. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

706. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

### C. A Guilty Plea and A Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin

707. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and

Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

708. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively to market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

**1. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion**

709. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

710. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, … and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

711. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[317]

712. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the

[317] *Id.*

DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

713. Further, since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

714. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

715. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law

enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

716. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

717. The New York Attorney General similarly found that Endo knew, as early as 2011 that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

718. As all of the governmental actions against the Marketing Defendants and against all the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

## XVII. FACTS PERTAINING TO CLAIMS UNDER ARIZONA RICO ACT

### A. The False Narrative Enterprise

#### 1. The Common Purpose and Scheme of the False Narrative Enterprise

719. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Marketing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

720. In order to unlawfully increase the demand for opioids, the Marketing Defendants formed an association-in-fact enterprise (the "False Narrative Enterprise") with the Front Groups and KOLs described above. Through their personal relationships, the members of the False Narrative Enterprise had the opportunity to form and take actions in furtherance of the False Narrative Enterprise's common purpose. The Marketing Defendants' substantial financial contribution to the False Narrative Enterprise, and the advancement of opioids- friendly messaging, fueled the U.S. opioids epidemic.[318]

721. The Marketing Defendants, through the False Narrative Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named "pseudoaddiction;" (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

722. The scheme devised, implemented and conducted by the RICO Defendants was a common course of conduct designed to ensure that the RICO Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Marketing Defendants' drugs. The Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the False Narrative

[318] *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

723. There was regular communication between the Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the False Narrative Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

724. At all relevant times, the Front Groups were aware of the Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the False Narrative Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

725. At all relevant times, the KOLs were aware of the Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for

the False Narrative Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

726. As public scrutiny and media coverage focused on how opioids ravaged communities in Arizona and throughout the United States, the Front Groups and KOLS did not challenge the Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the False Narrative Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

727. The Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the False Narrative Enterprise. As described herein, the False Narrative Enterprise's conduct in furtherance of the common purpose of the False Narrative Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

728. In addition to disseminating misrepresentations about the risks and benefits of opioids, the False Narrative Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the False Narrative Enterprise criticized or undermined the CDC Guidelines which represented "an important step - and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain."

729. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

730. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

731. The Marketing Defendants alone could not have accomplished the purpose of the False Narrative Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the False Narrative Enterprise could not have achieved its common purpose.

732. The impact of the False Narrative Enterprise's scheme is still in place - i.e., the opioids continue to be prescribed and used for chronic pain, and the epidemic continues to injure Plaintiff and consume Plaintiff's resources.

733. As a result, it is clear that the Marketing Defendants, the Front Groups, and the KOLs were all willing participants in the False Narrative Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

**2. The Conduct of the False Narrative Enterprise Violated Arizona's Civil RICO Statute**

734. From approximately the late 1990s to the present, each of the Marketing Defendants exerted control over the False Narrative Enterprise and participated in the operation or management of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use;

(ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

735. The False Narrative Enterprise had a hierarchical decision-making structure that was headed by the Marketing Defendants and corroborated by the KOLs and Front Groups. The Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States including Arizona. The Front Groups and KOLs in the False Narrative Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

736. The Front Groups also conducted and participated in the conduct of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

737. The Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[319] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[320]

[319] *Fueling an Epidemic* at 1.
[320] *Id.* at 2.

738. The KOLs also participated in the conduct of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the Marketing Defendants.

739. The scheme devised and implemented by the Marketing Defendants and members of the False Narrative Enterprise, amounted to a common course of conduct intended to increase the Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

### 3. The False Narrative Enterprise Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

740. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, AGS and ACPA. The Front Groups, which appeared to be independent, but were not, transmitted

the Marketing Defendants' misrepresentations. The Marketing Defendants and the Front Groups thus worked together to promote the goals of the False Narrative Enterprise.

741. The Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

742. Similarly, as discussed in detail above, the Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The Marketing Defendants and the KOLs thus worked together to promote the goals of the False Narrative Enterprise.

**4. Pattern of Unlawful Activity**

743. The Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of unlawful activity as described herein.

744. The pattern of unlawful activity used by the Marketing Defendants and the False Narrative Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful False Narrative Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the Marketing Defendants' misrepresentations.

745. Each of these fraudulent mailings and interstate wire transmissions constitutes unlawful acts and collectively, these violations constitute a pattern of unlawful activity, through which the Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Plaintiff.

746. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises,

or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Marketing Defendants and members of the False Narrative Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

747. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators and the public, including Plaintiff, the Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of unlawful activity.

748. The Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, such as hospitals transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

749. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

750. To achieve the common goal and purpose of the False Narrative Enterprise, the Marketing Defendants and members of the False Narrative Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the False Narrative Enterprise.

751. The Marketing Defendants, and each member of the False Narrative Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

752. Indeed, for the Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

753. The Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

**B. <u>The Opioid Supply Chain Participants</u>**

754. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort have categorically denied any criminal behavior or intent. Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, the Defendants (except for Insys) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

755. As "registrants" under the Arizona law, Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[321] Critically, these Defendants' responsibilities do not end with the products

[321] 21 C.F.R. 1301.74(b).

they manufacture or distribute -- there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity .

756. If morality and the law did not suffice, competition dictates that the Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under Arizona law this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the Arizona laws concerning controlled substances, and Arizona's RICO law.

757. The Defendants' scheme required the participation of all. If any one-member broke rank, its compliance activities would highlight deficiencies of the others, and their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the government authorities to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of government regulation and enforcement. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not

inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, Defendants apparently all found the same profit-maximizing balance - intentionally remaining silent to ensure the largest possible financial return.

758. As described above, at all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, Defendants jointly agreed to disregard their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market .

759. At all relevant times, as described above, the Defendants exerted control over, conducted and/or participated in the False Narrative Enterprise by fraudulently claiming that they were complying with their duties to maintain effective controls against diversion, including duties to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to generate unlawful profits.

760. The Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

c. they were complying with their obligation to report suspicious orders or diversion of their prescription opioids; and

d. they did not have the capability to identify suspicious orders of controlled substances.

761. The Defendants applied political and other pressure to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied for less stringent regulation of their marketing and distribution of pharmaceutical products.

762. The RICO Supply Chain Defendants are required to make reports of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

763. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports about suspicious orders, and/or omitted material information from reports, records and other document required to be filed. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to take responsive action. This failure included the failure to report this information to the government.

764. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

765. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

766. For the purpose of executing the illegal scheme, the Defendants committed unlawful acts, which number in the thousands, intentionally and knowingly, with the specific intent to advance the illegal scheme. These unlawful acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of unlawful activity.

767. The Defendants' use of the wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants,

or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

c. RICO Supply Chain Defendants' government registrations;

d. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' government registrations;

e. RICO Supply Chain Defendants' records and reports that were required to be submitted to regulatory authorities;

f. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

g. Documents for processing and receiving payment for prescription opioids;

h. Payments from the Distributors to the Marketing Defendants;

i. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

j. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

k. Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

l. Deposits of proceeds from the Defendants' manufacture and distribution of prescription opioids; and

m. Other documents and things, including electronic communications.

768. The Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or

interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

769. Each of the Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout Arizona and the United States.

770. The Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Arizona laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

771. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all Arizona regulations regarding the identification and reporting of suspicious orders of prescription opioids. The Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

772. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

773. The mail and wire transmissions described herein were made in furtherance of the Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their obligations under Arizona law to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market.

774. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include

thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

775. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

776. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

777. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

778. As described above, the Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the Defendants supports this conclusion that the Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports.[322]

[322] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

779. Each instance of unlawful activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims. The Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this State, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this State rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

780. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of unlawful activity.

**WAIVER OF CERTAIN CLAIMS FOR RELIEF**

781. Plaintiff expressly disclaims and waives any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation's ("McKesson") Pharmaceutical Prime Vendor Contract ("PPV Contract")[323] with the United States Department of Veteran Affairs. Plaintiff further commits that it will *not*, in any forum, rely on or raise the PPV Contract in connection with its allegations and/or prosecution in this matter.

782. Plaintiff agrees that should Defendants, present evidence sufficient for the trier of fact to determine that Plaintiff's injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Plaintiff was caused by goods or products distributed and/or services provided through the PPV.

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[323] More specifically, Tucson Medical Center expressly disclaims and waives any and all right to recover against the 17% state-wide opioid distribution, 28% southern Arizona opioid distribution and, 37.5% opioid distribution within Pima County under the terms and conditions of the PPV Contract. *See Tucson Medical Center v. Purdue Pharma L.P. et al*, No. 4:18-cv-00481, Doc. No. 38-1, p. 4, 5 (D. Ariz. Oct. 2, 2018).

## CLAIMS FOR RELIEF

## FIRST CLAIM FOR RELIEF

**Violation of RICO, A.R.S. § 13-2314.04 – Opioid False Narrative Enterprise (Against All Defendants)**

783. Tucson Medical Center repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 782 of this Complaint, as though fully set forth herein.

784. This Claim for relief alleges violations of A.R.S. § 13-2314.04(A).

785. At all relevant times, Tucson Medical Center was an entity capable of holding legal or beneficial interest in property.

### I. THE FALSE NARRATIVE ENTERPRISE

786. **Predicate Acts.** At all relevant times, Defendants conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity, by engaging in multiple, repeated, and continuous violations of:

(A) **A.R.S. § 13-2310 (A). Fraudulent Schemes and Artifices:** Any person who, pursuant to a scheme or artifice to defraud, knowingly obtains any benefit by means of false or fraudulent pretenses, representations, promises or material omissions is guilty of a class 2 felony. For purposes of this section, "scheme or artifice to defraud" includes a scheme or artifice to deprive a person of the intangible right of honest services. A.R.S. § 23-2310 (E). The presumptive sentence in Arizona for a class 2 felony is **5 years**. A.R.S. § 13-702 (D).

(B) **A.R.S. § 13-2311 (A). Fraudulent Schemes and Artifices; Willful Concealment.** Any person who, pursuant to a scheme or artifice to defraud or deceive, knowingly falsifies, conceals or covers up a material fact by any

trick, scheme or device or uses any false writing or document knowing such writing or document contains any false, fictitious or fraudulent statement or entry is guilty of a class 5 felony. The presumptive sentence in Arizona for a class 5 felony is **1.5 years**. A.R.S. § 13-702 (D); and

(C) **A.R.S. § 13-3417. Use of Wire Communication or Electronic Communication in Drug Related Transactions.** It is unlawful for a person to use any wire communication to facilitate the violation of any felony provision or to conspire to commit any felony provision of chapter 23 of this title. The presumptive sentence for violation of this statute in Arizona is in accordance with a class 5 felony, as such, the presumptive sentence is **1.5 years.** A.R.S. § 13-702(D). The Defendants, in violation of § 13-3417, transmitted communications electronically to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of asserting false claims through fraud and to engage in an intentional scheme to defraud Plaintiff, other health care providers, patients and their families and, in general, the American public; and

(D) **A.R.S. § 36-2531. "Prohibited Acts" under the Arizona Controlled Substances Act.** It is unlawful for a person "[t]o furnish false or fraudulent material information in, or omit any material information from, any application, report or other document required to be kept or filed under [… Title 36, C]hapter [27] or any record required to be kept by [… Title 36, C]hapter [27]." Records required to be kept under Chapter 36 include those enumerated in Title 32, Chapter 18, A.R.S. The presumptive sentence for violation of this statute in Arizona is in accordance with a class 4 felony, as such, the presumptive sentence is **2.5 years.** A.R.S. § 13-702(D).

787. Defendants' violations of A.R.S. §§ 2310(A), 2311(A) and 3417 constitute acts of "racketeering" as that term is defined in, A.R.S. §§ 12-2301(D)(4). Specifically, Defendants

asserted false claims, including false claims asserted through fraud, § 12-2301(D)(4)(xv); and engaged in a scheme or artifice to defraud, § 12-2301(D)(4)(xx)

788. **Pattern of Unlawful Activity.** At least two unlawful acts as defined in § 13-2301, subsection D, paragraph 4, subsection (b), item (iv), (v), (vi), (vii), (viii), (ix), (x), (xiii), (xv), (xvi), (xviii), (xix), (xx), (xxvi) meet the following requirements: (i) The last act of unlawful activity that is alleged as the basis of the claim occurred with five years of a prior act of unlawful activity; (ii) The unlawful acts that are alleged as the basis of the claim were related to each other or to a common organizing principle, including the affairs of an enterprise. Unlawful acts are related if they have the same purposes, results, participants, victims or methods of commission or otherwise interrelated by distinguishing characteristics; and (iii) The unlawful acts that are alleged as the basis of the claim were continuous or exhibited the threat of being continuous. A.R.S. §§ 13-2314.04 (T)(3)(a) i-iii. The False Narrative Enterprise committed the following predicate offenses: (xv) Asserting false claims, including false claims asserted through fraud; (xx) A scheme or artifice to defraud.

789. At all relevant times, Defendants, in violation of the above statutes, conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity, by engaging in multiple, repeated, and continuous violations of Arizona law proscribing fraudulent schemes and the concealment thereof, A.R.S. §§ 13-2310-11, Arizona law proscribing electronic communications in connection with drug transactions, A.R.S. § 13-3417 and Arizona's Uniform Controlled Substances Act, § 36-2501, *et seq.* The Defendants transmitted electronic communications to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud Plaintiff, other hospitals, health care providers, patients and their families and, in general, the American public.

790. **Structure of the False Narrative Enterprise:** The False Narrative Enterprise reflected several types of participants, not all of which were complicit, and not all of which are named herein as Defendants:

(A) **Name.** For the purpose of this Complaint, the name of the "enterprise" is the False Narrative Enterprise.

(B) **Purpose.** The purposes of the False Narrative Enterprise were twofold, one lawful and one unlawful; the lawful purpose of the False Narrative Enterprise was to engage in the manufacture and sale of pharmaceutical products in interstate and foreign commerce; the unlawful purpose of the False Narrative Enterprise was in engage in and carry out an intentional scheme to defraud purchasers, including doctors and hospitals, by propagating falsehoods about the safety, benefits, and risks of opioids.

(C) **Continuity.** The continuity of the False Narrative Enterprise was coterminous with the period of time necessary to defraud Plaintiff, physicians, other healthcare providers, patients and their families, and the American public in general.

(D) **Effect on Commerce.** During the relevant times, the False Narrative Enterprise was engaged in, and affected, interstate and foreign commerce, as stated in this Complaint.

(E) **The Marketing Defendants**. The Marketing Defendants are Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt. The Marketing Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products.

(F) **The Front Groups.** The Marketing Defendants used the Front Groups, such as the American Pain Foundation, American Academy of Pain Medicine, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, the American Geriatrics Society, and the American Chronic Pain Association, not named as defendants herein and not all of which were fully complicit, to stoke demand

for opioids by falsely creating the impression of independent third party authoritative validation of the false claims of the Marketing Defendants.

(G) **The KOLs**. The Marketing Defendants used KOLs, such as Dr. Portenoy, Dr. Webster, Dr. Fine and Dr. Fishman, not named as defendants herein and who may not have been fully complicit, to provide ostensibly valid, third party, authoritative validation of the false claims of the Marketing Defendants.

(H) **The Distributor Defendants.** The Distributor Defendants are Cardinal, AmerisourceBergen; they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king-size profits reaped from the sale of opioids to addicts, deliberately ignoring their legal obligations.

(I) **Corrupt Physicians and Pharmacies, a/k/a the Pill Mills.** These participants, although not named as defendants herein, prescribed opioids illegally and with no basis in legitimate medicine, and dispensed opioids illegally and in direct violation of their legal obligations

(J) **The National Retail Pharmacies.** The National Retail Pharmacies, although not named as defendants herein, are CVS, Safeway, Walgreens, Albertson's, Frys and Wal-Mart. Like the Distributor Defendants, they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their legal obligations.

791. In violation of Section 13-2314.04 of RICO, A.R.S. § 13-2314.04(A), the Defendants, with full knowledge and purpose, conspired to violate Section 13-2314.04 (A) of RICO. The wrongful conduct committed by employees and other agents of the Defendants was

performed, authorized, requested, commanded, ratified and/or recklessly tolerated by directors and/or high managerial agents of the Defendants. Upon reasonable discovery the names of the directors and high managerial agents who participated will become known.

## II. CONSEQUENCES

792. By reason of the above-referenced violations of Section 13-2314.04 (A) RICO, A.R.S. § 13-2314.04(A). Plaintiff was injured in its business or property within A.R.S. § 132314.04(A) of RICO, including but not limited to, damages for the costs of opioids which it was induced to purchase that it otherwise would not have, and to recover threefold the damages it sustained as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief as this Court deems just and proper.

## SECOND CLAIM FOR RELIEF

### Violation of Arizona's Consumer Fraud Act (A.R.S. § 44-1522) (Against All Defendants)

793. Plaintiff repeats, realleges, and incorporates by reference the allegations in Paragraphs 1 through 792 of this Complaint, as though fully set forth herein.

794. This cause of action is brought pursuant to Section 44-1522, Arizona Statutes, which is known as Consumer Fraud Act.

795. The act, use or employment of any person of any deception, deceptive or unfair act or practice, fraud, false pretense, misrepresentation, or concealment, suppression or omission of any material fact with the intent that other rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice. A.R.S. § 44-1522(A).

796. The Arizona Consumer Fraud Act is a broad act intended to eliminate unlawful practices. *Holeman v. Neils*, 803 F.Supp. 237, 242 (D. Ariz. 1992). The act further provides that it be construed consistent with the Federal Trade Commission Act, 15 U.S.C.A. § 55(a)(1), which states:

> The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only the representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the commodity to consequences which may result from the use of the commodity to which the advertisement related under the conditions prescribed in said advertisement, or such conditions as are customary or usual. No advertisement of a drug shall be deemed false if it is disseminated only to members of the medical profession, contains no false representation of material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

797. "The term 'deceptive' has been interpreted to include representations that have a 'tendency and capacity' to convey misleading impressions to consumers even though interpretations that would not be misleading also are possible. The meaning and impression are to be taken from all that is reasonably implied, not just from what is said, and in evaluating the representations, the test is whether the least sophisticated reader would be misled." *Madsen v. Western American Mortg. Co.*, 694 P.2d 1228, 1232 (Az.Ct.App. 1985) (internal quotations omitted).

798. Tucson Medical Center qualifies as a "person" within the meaning of Arizona Statute 44-1521(6).

799. All Defendants qualify as "person[s]" under A.R.S. § 44-1521(6), and committed acts of deception and unfair practices in their sale and advertisements.

800. Defendants engaged in deception, deceptive or unfair acts or practices, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of prescription drugs in violations of the Arizona Consumer Fraud Act, A.R.S. § 44-1522(A).

801. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the Arizona Consumer Fraud statute by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

802. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required Arizona's Uniform Controlled Substances Act, A.R.S. § 36-2501, *et seq.*, Arizona rules A.A.C. R4-23-604 and A.A.C. R4-26-605, and laws incorporated therein.

803. Defendants' unfair or deceptive acts or practices in violation of the Arizona Consumer Fraud Act offend Arizona's public policy, are immoral, unethical[324], oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Plaintiff. Plaintiff risks irreparable injury as a result of the Marketing and Distributor Defendants', and their agents', acts, misrepresentations and omissions in violation of the Arizona Consumer Fraud Act, and these violations present a continuing risk to Plaintiff, as well as to the general public.

804. As a direct and proximate result of Defendants' violations of the Arizona Consumer Fraud Act, Plaintiff has suffered and continues to suffer injury-in-fact and actual damages.

805. Defendants violated the Arizona Consumer Fraud Act because they engaged in false or misleading statements about the efficacy and safety of opioid pharmaceuticals.

806. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made misrepresentations, omissions, or suppressed material

[324] A.R.S. § 32-1901.01(A)(26)

facts to Plaintiff with the intent induce it to purchase, administer, and consume opioids as set forth in detail above.

807. Defendants knew at the time that they made their misrepresentations and omissions that they were false and/or misleading.

808. Defendants intended that Plaintiff, physicians, patients, and/or others would rely on their misrepresentations and omissions.

809. Plaintiff, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

810. Plaintiff would not have purchased the quantity of opioids it had from Defendants had it known the truth about Defendants' misrepresentations and omissions.

811. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

812. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff, physicians, patients, and/or others suffered actual pecuniary damage.

813. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

814. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

## THIRD CLAIM FOR RELIEF

### Negligence
### (Against All Defendants)

815. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 814 of this Complaint, as though fully set forth herein.

816. To establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and loss or damage caused by the breach, and actual loss or damage to another. All such essential elements exist here.

817. Each Defendant had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs.

818. Each Defendant breached its aforesaid duties by its conduct previously specified herein.

819. As a proximate result, Defendants have caused Plaintiff's injury related to the treatment of opioid-related conditions. Plaintiff has incurred massive costs by providing uncompensated care as a result of opioid-related conditions.

820. Each Defendant owed its aforesaid duties to Plaintiff because the injuries alleged herein were foreseeable by the Defendants.

821. The injuries to Plaintiff would not have happened in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture, marketing, sale and distribution of opioids.

822. Plaintiff seeks compensatory damages for its monetary losses previously specified herein, plus interest and the costs of this action.

## FOURTH CLAIM FOR RELIEF

### Wanton Negligence
### (Against All Defendants)

823. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 822 of this Complaint, as though fully set forth herein.

824. Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably or most probably result in injury to others, specifically hospitals such as Tucson Medical Center, which would be subjected to providing unreimbursed healthcare treatment to patients with opioid conditions.

825. As a proximate result of Defendants' wanton negligence, Plaintiff was monetarily damaged as aforesaid.

826. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

**FIFTH CLAIM FOR RELIEF**

**Negligence Per Se**
**(Against All Defendants)**

827. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 826 of this Complaint, as though fully set forth herein.

828. Defendants violated requirements of Arizona's Uniform Controlled Substance Act, A.R.S. § 36-2501, *et seq.*, by knowingly or intentionally failing to institute adequate controls of the distribution of controlled substances and, furnishing false or fraudulent information in, and/or omitting material information from documents filed with the government.

829. Defendants have a duty to comply with the regulations of A.R.S. § 44-1522 and A.R.S. § 36-2501, *et seq*.

830. Failure to comply with the Arizona statutory and common law obligations constitutes negligence *per se.*

831. Defendants failed to comply with the Arizona Consumer Fraud Act and other Arizona laws.

832. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Arizona law.

833. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

834. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances and thereby creating and continuing addictions to prescription medications in Arizona.

835. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Tucson Medical Center by violating Arizona law, by creating conditions which contribute to the violations of Arizona laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

836. Plaintiff has suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Arizona law.

837. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

838. Plaintiff is within the class of persons the Arizona Consumer Fraud Act and the Arizona Board of Pharmacy rules were intended to protect.

839. The harm that has occurred is the type of harm that the Arizona Consumer Fraud Act, the Arizona Board of Pharmacy rules were intended to guard against.

840. Defendants breached their duty by failing to take any action to prevent or reduce the distribution of the opioids.

841. As a direct and proximate result of Defendants' negligence *per se*, Tucson Medical Center has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids.

842. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

843. Defendants were negligent in failing to monitor against diversion of opioid pain medications.

844. Defendants' violations constitute negligence *per se*.

845. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

## SIXTH CLAIM FOR RELIEF

### Negligent Marketing
### (Against Marketing Defendants)

846. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 845 of this Complaint, as though fully set forth herein

847. Defendants had a duty to exercise reasonable care in the marketing of opioids.

848. Defendants were aware of the potentially dangerous situation involving opioids.

849. Defendants marketed opioids in an improper manner by:

a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;

c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;

e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

850. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

851. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions

listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

852. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

853. Defendants knew or should have known that opioids were unreasonably dangerous and could cause addiction.

854. Defendants have a duty to exercise reasonable care in the distribution, promotion and marketing or opioids.

855. Defendants breached their duty by failing to take any action to prevent or reduce the unlawful distribution of opioids.

856. Defendants' marketing was a factor for physicians, patients, and others to prescribe or purchase opioids.

857. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and care of addiction or risk of addiction to opioids.

858. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

## SEVENTH CLAIM FOR RELIEF

### Negligent Distribution
### (Against All Defendants)

859. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 858 of this Complaint, as though fully set forth herein.

860. Defendants had a duty not to breach the standard of care established under Arizona law and its implementing regulations, and to exercise reasonable care in the distribution of opioids.

861. Defendants were aware of the potentially dangerous situation involving opioids.

862. Defendants distributed opioids in an improper manner by:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against diversion;

c. Choosing not to, or failing to, effectively monitor for suspicious orders;

d. Choosing not to, or failing to, report suspicious orders;

e. Choosing not to, or failing to stop or suspend shipments of suspicious orders; and

f. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

863. Defendants' negligent breach of their duties resulted in foreseeable harm and injury to Plaintiff.

864. As a direct and proximate result of Defendants' negligence, Plaintiff suffered and will continue to suffer damages including costs related to uncompensated care and other costs related to the distribution of opioids which never should have been sold.

865. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

## EIGHTH CLAIM FOR RELIEF

**Nuisance**
**(Against All Defendants)**

866. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 865 of this Complaint, as though fully set forth herein.

867. The nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic area served by Plaintiff for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

868. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and other fraudulent schemes as described herein, created and maintained the opioid epidemic in Plaintiff's community, which is harmful and disruptive to and substantially and unreasonable annoys, injuriously affects, endangers, and interferes with the safety, health, morals, comfort, and general welfare of the public.

869. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiff, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

870. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

871. Defendants' activities unreasonably interfere with the economic rights of Plaintiff.

872. The Defendants' interference with these rights of Plaintiff is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Tucson Medical Center;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiff serves;

c. Is proscribed by statutes and regulation, including the consumer protection statute;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Defendants have reason to know their conduct has a significant effect upon Plaintiff; and

f. Has inflicted substantial costs on Plaintiff.

873. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

874. The resources of Plaintiff are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

875. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

876. Defendants knew of the public health hazard their conduct would create. It was foreseeable to Defendants that their conduct would unreasonably interfere with the ordinary comfort, use, and enjoyment of residents within the State of Arizona.

877. Defendants' conduct is unreasonable, intentional, unlawful, reckless, or negligent.

878. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiff and in the geographic area served by Plaintiff.

879. As a direct and proximate result of the nuisance, Plaintiff has sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving it to the Plaintiff and other hospitals the costs of cleaning it up. This is a classic nuisance.

880. As a result of Defendants' actions, Plaintiff has suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely that Plaintiff has provided uncompensated care for patients suffering from opioid-related conditions.

881. The public nuisance – i.e. the opioid epidemic – created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

882. Defendants should be required to pay the expenses Plaintiff has incurred or will incur in the future to fully abate the nuisance.

883. Therefore, Plaintiff demands judgment in its favor against the Defendants for injunctive relief, abatement of the public nuisance, and for damages in an amount to be determined by a jury, together with all cost of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

## NINTH CLAIM FOR RELIEF

### Unjust Enrichment
### (Against All Defendants)

884. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 883 of this Complaint, as though fully set forth herein.

885. Plaintiff provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating. Plaintiff thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

886. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, hospitals throughout the

United States to provide unreimbursed healthcare treatment to patients with opioid conditions that Defendants were responsible for creating.

887. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

888. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

889. Defendants have therefore been unjustly enriched.

890. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiff.

## TENTH CLAIM FOR RELIEF

### FRAUD AND DECEIT
### (Against All Defendants)

891. Plaintiff repeats, realleges and incorporates by reference the allegations set forth in Paragraphs 1 through 890 of this Complaint, as though fully set forth herein.

892. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements, and by intentionally and unlawfully omitting and/or concealing information.

893. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout Arizona and the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

894. Specifically, the Marketing Defendants' knowingly deceptions during the relevant period, which were intended to induce reliance, include but are not limited to:

a. Marketing Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids in chronic pain;

b. Marketing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;

c. Marketing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

d. Marketing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;

e. Marketing Defendants misrepresentations that screening tools effectively prevent addiction;

f. Marketing Defendants; misrepresentations concerning the comparative risks of NSAIDs and opioids;

g. Marketing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

h. Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;

i. Marketing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

j. Marketing Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;

k. Marketing Defendants' misrepresentations that withdrawal is easily managed;

l. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;

m. Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;

n. Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;

o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;

p. Insys's misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

q. Insys's misrepresentations to third-party payors to secure approval for coverage;

r. Insys's use of speaker bureaus to disguise kickbacks to prescribers;

s. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

t. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;

u. Marketing Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;

v. Marketing Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,

w. Such other misrepresentations and deceptions outlined above.

895. By engaging in the acts and practices alleged herein, Marketing Defendants, in the relevant time period, with the intent that others rely on their omissions or suppression of information, omitted material facts that Marketing Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

a. Opioids are highly addictive and may result in overdose or death;

b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. High dose opioids subject the user to greater risks of addiction, other injury, and/or death;

d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;

e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;

h. Marketing Defendants' failure to report suspicious prescribers and/or orders;

i. Insys's use of kickback and insurance fraud schemes;

j. Insys's failure to disclose that Subsys was not approved for non-cancer pain;

k. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain;

l. Marketing Defendants' failure to disclose their financial ties to and role in connection with KOLs, front groups, and deceptive literature and materials, as more fully described above; and

m. Such other omissions and concealments as described above in this Complaint.

896. In each of the circumstances described *inter alia* the foregoing paragraph, Marketing Defendants knew that their failure to disclose rendered their prior representations untrue or misleading.

897. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiff because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiff, its agents, its community, physicians, and the public.

898. Marketing Defendants intended and had reason to expect under the operative circumstances that Plaintiff, its agents, its community, physicians, and persons on whom Plaintiff and its agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiff would act or fail to act in reasonable reliance thereon.

899. Marketing Defendants intended that Plaintiff, its agents, its community, physicians, and persons on whom Plaintiff and its agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiff to suffer loss.

900. The Marketing Defendants were not alone in this, the Distributor Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. These deceptions include but are not limited to:

a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;

b. Acknowledgment of the Distributor Defendants that because of their unique position within the "closed" system, they were to act as the first line of

defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;

c. Cardinal Health claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;"

d. AmerisourceBergen took a same position as its counterpart within the industry and stated that it was "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;"

e. More holistically, Distributor Defendants misrepresented that not only do its members (Distributor Defendants) have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society;

f. Such other omissions or concealments as described above in this Complaint.

901. By engaging in the acts and practices alleged herein, Distributor Defendants, in the relevant time period, with the intent that others rely on their omissions or suppression of information, omitted material facts that Distributor Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiff's community;

b. That they failed to report suspicious orders;

c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;

d. That they failed to prevent against diversion from legitimate to non-legitimate channels;

e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;

f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances; and

g. Such other omissions or concealments as alleged above in this Complaint.

902. Distributor Defendants intended and had reason to expect under the operative circumstances that Plaintiff, its agents, community, physicians, and persons on whom Plaintiff relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiff would act or fail to act in reasonable reliance thereon.

903. Distributor Defendants intended that Plaintiff, its agents, community, physicians, and persons on whom Plaintiff and its agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiff to suffer loss.

904. Plaintiff rightfully, reasonably, and justifiably relied on Marketing Defendants' representations and/or concealments, both directly and indirectly. As the Marketing Defendants knew or should have known Plaintiff was directly and proximately injured as a result of this reliance, Plaintiff's injuries were directly and proximately caused by this reliance.

905. As a result of these representations and/or omissions, Plaintiff proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and effective response to the opioid epidemic.

906. Plaintiff would not have purchased the quantity of opioids it had from Defendants had it known the truth about Defendants' false representations and omissions.

907. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

908. Defendants' misconduct alleged in this case is ongoing and persistent.

909. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort Plaintiff would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

910. Plaintiff has incurred expenditures for special programs over and above ordinary hospital healthcare services.

911. These Defendants' conduct was accompanied by wanton and willful disregard of person who foreseeably might be harmed by their acts and omissions.

912. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

913. Plaintiff has suffered monetary damages as aforesaid. As such Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants. Attorney fees and costs, and pre- and post-judgment interest.

## ELEVENTH CLAIM FOR RELIEF

### Civil Conspiracy to Commit Fraud and Maintain a Nuisance
**(Against All Defendants)**

914. Plaintiff repeats, realleges and incorporates by reference the allegations set forth in Paragraphs 1 through 913 of this Complaint, as though fully set forth herein.

915. "For a civil conspiracy to occur two or more people must agree to accomplish an unlawful purpose or to accomplish a lawful object by unlawful means, causing damages." *Baker v. Stewart Title & Trust of Phoenix*, 5 P.3d 249, 256 (Ariz. App. Ct. 2000). "In short, liability for civil conspiracy requires that two or more individuals agree and thereupon accomplish 'an underlying tort which the alleged conspirators agreed to commit.'" *Wells Fargo Bank v. Arizona Laborers, Teamsters and Cement Masons Local No. 395 Pension Trust Fund*, 38 P.3d 12, 36 (Ariz. 2002) (quoting *Baker*, 5 P.3d at 259).

916. Conspirators are liable for any tortious act, even unknown, committed in furtherance of the conspiracy, including acts not personally committed. *Baker*, 5 P.3d at 256.

917. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids in Arizona and Plaintiff's community.

918. Defendants engaged in a civil conspiracy, in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Arizona and Plaintiff's community, to (1) commit fraud and misrepresentation, and (2) maintain a public nuisance.

919. Defendants each conspired with various KOLs and Front Groups to commit unlawful or lawful acts in an unlawful manner. Defendants and the various KOLs and Front Groups with which each of them was allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote and distribute opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase the sale and distribution of opioids, and Defendants—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

920. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities

in creating and disseminating these publications is further evidence of each conspiracy's existence.

921. By engaging in the conduct described in this Complaint, Defendant Endo agrees with Front Groups APF, NICP, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NICP, AGS and FSMB's deceptive statements promoting opioids and APF, NICP, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF), *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra.* They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publication, CMEs, and websites is further evidence of each conspiracy's existence.

922. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and APF), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies and the collaboration between Janssen

and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

923. By engaging in the conduct described in this Complaint, Defendant Purdue agreed with Front Groups APF, FDMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),[325] *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CME's and websites is further evidence of each conspiracy's existence.

924. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Plaintiff in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

[325] Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

925. Each of the participants to the conspiracies outlined above was aware of the nuisance resulting from their conduct, and agreed to continue the practices described above that resulted in the maintenance of that nuisance.

926. Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their legal duties to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

927. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the attention of government authorities. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with governmental authorities.

928. The Defendants further worked together in their unlawful failure to act to prevent diversion and failure to monitor for, report, and prevent suspicious order of opioids.

929. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

930. By reason of Defendants' unlawful acts, Plaintiff has been damaged and continues to be damaged by paying the costs of Defendants externalities and has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

931. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

932. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

933. As outlined above, Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was and unrelenting stream of misleading information about compliance with state and federal legislation as related to opioid distribution, and the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers and consumers. Defendants exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

934. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

935. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

936. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

937. Defendants' misconduct alleged in this case is ongoing and persistent.

938. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergent of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

939. Plaintiff has incurred expenditures for special programs over and above ordinary healthcare services.

940. Because of Defendants dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with Arizona law concerning the distribution of opioids, Defendants are responsible for the costs.

941. Plaintiff therefore requests this Court to enter an order awarding judgment in its favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiff such other, further, and different relief as this Court may deem just and proper.

## TWELFTH CLAIM FOR RELIEF

### Fraudulent Concealment
### (Against All Defendants)

942. Plaintiff repeats, realleges and incorporates by reference the allegations set forth in Paragraphs 1 through 941 of this Complaint, as though fully set forth herein.

943. "One party to a transaction who by concealment or other action intentionally prevents the other from acquiring material information is subject to the same liability to the other, for pecuniary loss as though he had stated the nonexistence of the matter that the other was thus prevented from discovering." Restatement (Second) of Torts § 550 (1977).

944. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material fact and knowledge to Plaintiff to induce it to purchase and administer opioids as set forth in detail above.

945. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addition and death; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were misrepresentations of facts material, Defendants have engages in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

946. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiff would rely on their misrepresentations, and that such reliance would cause harm to Plaintiff.

947. Plaintiff reasonably relied on Defendants' misrepresentations and omissions in writing and filling prescriptions for Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

948. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

949. Plaintiff suffered actual pecuniary damages proximately caused by Defendants concealment of material fact, which include but are not limited to, expending funds on emergency services, emergency response, additional training, additional security, and other services Plaintiff would not have incurred.

950. Plaintiff has incurred expenditures for special programs over and above their ordinary hospital services.

951. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's existence. Plaintiff alleges wrongful acts which were neither discrete nor of the sort a hospital can reasonable expect.

952. Plaintiff therefore demands judgment in its favor against Defendants for compensatory, exemplary, and punitive damages in an amount to be determined by a jury, together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff asks that the Court:

A. Enter judgment against Defendants, jointly and severely, and in favor of Plaintiff;

B. Award damages for the costs of the quantity of opioids Plaintiff was induced to purchase from Defendants;

C. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages; treble damages; punitive damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate, including disgorgement of illicit proceeds and other orders as provide in A.R.S. § 13-2314.04;

D. Award Plaintiff their cost of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the Court may deem just and proper under the circumstances.

**JURY DEMAND**

Plaintiff demands a trial by jury on all issues so triable.

Dated: October 9, 2018

Respectfully Submitted,

/s/ *Steven C. Mitchell*
Steven C. Mitchell (AZ Bar No. 009775)
Samuel F. Mitchell
(*pro hac vice* to be submitted)
**MITCHELL & SPEIGHTS,** LLC

4854 E. Baseline Road, Suite 103
Mesa, AZ 85206
Tel: (602) 244-1520
Fax: (602) 267-9394
steve@mitchellspeights.com
sam@mitchellspeights.com

Linda Singer
(*pro hac vice* to be submitted)
**MOTLEY RICE LLC**
401 9th Street NW
Suite 1001
Washington, DC 20004
Tel: (202) 386-9626
Fax: (202) 386-9622
lsinger@motleyrice.com

John W. ("Don") Barrett
(*pro hac vice* to be submitted)
P.O. Box 927
404 Court Square North
Lexington, MS 39095
Tel: (662) 834-2488
Fax: (662) 834-2628
dbarrett@barrettlawgroup.com

G. Robert Blakey
WILLIAM J. & DOROTHY T. O'NEILL PROFESSOR OF LAW EMERITUS
NOTRE DAME LAW SCHOOL*
7002 East San Miguel Avenue
Paradise Valley, Arizona 85253
Ph: 574-514-8220
E-mail: blakey.1@nd.edu
*For purposes of identification only